IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No.: 06-222 JJF **PUBLIC VERSION**

DEFENDANT IMPAX LABORATORIES, INC.'S OPPOSITION TO PLAINTIFF WYETH'S MOTION FOR PROTECTIVE ORDER TO STRIKE AND LIMIT THE SCOPE OF AMENDED NOTICE OF DEPOSITION OF WYETH PURSUANT TO FED. R. CIV. P. 30(b)(6)

RICHARD K. HERRMANN (I.D. No. 405)
MARY B. MATTERER (I.D. No. 2696)
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Ave., 10th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800
mmatterer@morrisjames.com

M. PATRICIA THAYER (*pro hac vice*)
JOHN M. BENASSI (*pro hac vice*)
JESSICA R. WOLFF (*pro hac vice*)
DANIEL N. KASSABIAN (*pro hac vice*)
SAMUEL F. ERNST (*pro hac vice*)
HELLER EHRMAN LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92101
Telephone: (858) 450-8400
Facsimile: (858) 450-8499

Attorneys for Defendant IMPAX LABORATORIES, Inc.

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I. NATURE AND STAGE OF PROCEEDINGS

This is a Hatch-Waxman patent infringement action instituted by Wyeth, in which it asserts that three patents are infringed by venlafaxine extended release formulations of Impax Laboratories, Inc. ("Impax"), even though these patents describe a very different formulation and, if broadly construed beyond their disclosures, are anticipated and obvious in light of the prior art. Wyeth's Motion for Protective Order to Strike and Limit The Scope of Impax's Amended Notice of Deposition of Wyeth Pursuant to Fed. R. Civ. P. 30(b)(6) ("Wyeth's Motion") is calculated, at a minimum, to delay discovery and potentially postpone this Court's consideration of the merits of Impax's strong defenses. More importantly, it seeks to prevent Impax from gathering the evidence that will prove those defenses. Thus, Wyeth's Motion should be denied.

II. SUMMARY OF ARGUMENT

1. Wyeth's Motion asserts that Defendant Impax Laboratories, Inc.'s Amended Notice of Deposition of Wyeth Pursuant to Fed. R. Civ. P. 30(b)(6) (the "Amended Notice") is overbroad. First, this assertion must be examined in the context of the issues and facts interjected into this case as a result of Wyeth's affirmative contentions. For example, Wyeth asserts that its patent claims are not limited to the specific "extended release formulation" actually disclosed in the patents' specification, and relies expansively on its clinical testing in support of its broad claim construction. Impax must conduct discovery on all such contentions. Second, when many key Wyeth employees were deposed in the prior litigation on these same patents, *Wyeth v. Teva Pharmaceuticals USA Inc.*, No. 03-cv-01293 (D.N.J.) ("the *Teva* litigation"), they were unable to answer highly relevant questions because of faded memories that were not refreshed during preparation by Wyeth's counsel, or because they were prevented by Wyeth's counsel from answering. To conduct efficient and effective discovery, and to avoid deposing individuals without knowledge, Impax has chosen to begin its deposition discovery by way of a Rule 30(b)(6) deposition with particularized topics, to discover

Wyeth's corporate knowledge of key facts relevant to this case, and to determine who at Wyeth still has personal knowledge of those facts. *See* Part IV.A, *infra*.

2. Wyeth's Motion asserts that the topics selected by Impax amount to improper contention discovery. That is not so. As to the topic regarding conception of the invention(s) claimed in the patents-in-suit, for example, REDACTED but has failed to provide any further details. Impax should be permitted to explore the facts—e.g., what actually transpired on REDACTED, who was present, what was discussed, was it considered significant at the time, and why. As to the topic regarding the denials and statements in Plaintiff Wyeth's Reply to First Amended Counterclaims of Defendant Impax Laboratories, Inc. ("Wyeth's Reply to Counterclaims") [D.I. 46], it is not seeking contentions, but the facts regarding Wyeth's prosecution of the patents-in-suit, and Wyeth's affirmative factual assertions in its response to Impax's defenses. *See* Part IV.B, *infra*.

3. Impax does not seek privileged information, but instead seeks the basis by which privilege is being asserted and other non-privileged information regarding the drafting and prosecution of the patents-in-suit. Wyeth uses overbroad and deficient claims of privilege and immunity to "block" discovery of this discoverable evidence relevant to Impax's inequitable conduct and patent misuse defenses. Because Impax has asserted these defenses, which make relevant the mental impressions of the prosecuting, in-house attorneys as well as Wyeth's patent policies, Impax must be allowed ascertain all non-privileged information with respect to the same. *See* Part IV.C, *infra*.

4. Wyeth's Motion is an attempt to unduly delay discovery in this case. This is evinced, *inter alia*, by Wyeth's refusal to produce a witness on any noticed topic—even those that it agrees are relevant—until the instant motion is ruled upon. *See* Part IV.D, *infra*.

III. STATEMENT OF FACTS

A. Wyeth's Delay In Producing Documents And Responding To Interrogatories

Impax diligently pursued other means of discovery on the topics on which it seeks to depose Wyeth, only to face delays, objections, and insufficient responses from Wyeth. Below are examples of this pattern in practice as it pertains to (1) Impax's attempts to analyze discovery in the *Teva* litigation, and (2) its efforts to obtain basic information about the conception and reduction to practice of the claimed invention(s) of the patents-in-suit.

1. Wyeth's delay in producing the *Teva* litigation documents

On June 23, 2006, Impax propounded document requests seeking (1) Wyeth's document production in the *Teva* litigation, (2) the document requests propounded by Teva that resulted in that production (so as to have context), (3) transcripts and exhibits of Wyeth's witnesses deposed in the *Teva* litigation, and (4) materials related to the claim construction hearing in the *Teva* litigation. [Ex. A.] In its responses served July 26, 2006, Wyeth agreed to produce responsive documents, but it unilaterally set forth as a condition that Impax must pay in advance for this production, including those documents previously produced in the *Teva* litigation, such as Wyeth's New Drug Application ("NDA") for Effexor XR. [Ex. B, at 4-6.] Even though Impax agreed to pay under protest for the production of the NDA in order to obtain any responsive documents prior to the Court's initial August 10th deadline to amend the pleadings, Wyeth still delayed its production. [Exs. C & D.] Only after this deadline did the production of other documents from the *Teva* litigation begin to trickle-out, with the majority of this production sent on the Court's October 10th deadline for document production [*E.g.*, Exs. E, F & G], and the remaining documents sent only last week [Ex. H].

2. Wyeth's delay and refusal to provide relevant information

On June 30, 2006, Impax propounded additional discovery requests that included interrogatories seeking, *inter alia*, (1) identification of persons with knowledge of the

conception and reduction to practice of the claimed invention(s) of the patents-in-suit, the contributions of these persons to those events, and the dates on which those events occurred, and (2) identification of those persons involved in the research and development of Effexor XR, which Wyeth asserts as embodying the asserted claims. [Ex. I, Interrog. Nos. 2-3, 12.] Wyeth's initial responses to these interrogatories, served on July 31, 2006, listed only REDACTED who contributed to the claims or participated in the development of Effexor XR. Wyeth also refused to describe REDACTED, asserting such information was irrelevant, and further refused to even provide REDACTED claiming this was the subject of expert opinion. [Ex. J, Resps. to Interrog. Nos. 2-3, 12.] Only after numerous meet and confer correspondence, and in light of the Court's October 10th deadline to respond to contention interrogatories, did Wyeth concede that it needed to provide more. It supplemented its responses as follows:

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[Ex. K, Suppl. Resp. to Interrog. No. 12.] Wyeth failed to provide any more information REDACTED

B. Impax Reviewed Transcripts From The *Teva* Litigation And Determined That Many Key Witnesses Did Not Provide Meaningful Testimony

Upon its receipt of deposition transcripts for Wyeth's fact witnesses in the *Teva* litigation, Impax reviewed them in order to avoid duplication in this case. However, this review resulted in two conclusions as to the persons that appeared to be participants in (A) the development of Effexor XR, (B) the conception and reduction of the claimed invention(s) of the patents-in-suit, (C) the prosecution of the patents-in-suit, or (D) prior art extended release formulation work by Wyeth: (1) The witnesses had major memory lapses, or (2) they were prevented from testifying by Wyeth's counsel.

Specifically, these deponents could not recall (or were not sufficiently prepared so as to recall) basic information, much less key details.

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Second, as to information that touched on the patentability of Wyeth's venlafaxine extended release work, and Wyeth's general policies and practice for seeking patents, Wyeth's counsel instructed witnesses not to answer even foundational questions to determine if a privilege existed. [*E.g.*, Ex. P, at 60:2-90:4.] Indeed, Wyeth's counsel at times indicated that it was going to "block" questions even as to non-privileged information, such as the inventor's extended release work for other drug compounds (despite a protective order allowing such to disclosed to outside counsel only).

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C. Impax Propounds Its Notice Of Wyeth's Deposition And Wyeth Refuses To Comply Even As To Topics It Concedes Are Proper

On November 20, 2006, in light of its review of the *Teva* litigation transcripts, the endless meet and confer on interrogatories and other written discovery, and with claim construction briefing to take place in the Spring of 2007, Impax noticed Wyeth's deposition on 69 topics regarding the claimed invention(s) of three patents-in-suit (which

were prosecuted over the course of six years), and the development of specific extended release formulations by Wyeth REDACTED Impax also asked to commence the deposition in December 2006. [Ex. Q.] Wyeth objected to each and every topic in this notice. [Wyeth's Mot. Ex. 3.] In an effort to see a quick end to Wyeth's meet and confer game, Impax served its Amended Notice on January 22, 2007, and suggested that the parties move forward with certain topics on February 5, 2007. [*Id.* Ex. 1; Ex. R.] Even though the Amended Notice set forth only 34 topics, with sufficient particularity to avoid objections as to ambiguity, Wyeth again objected to all but 5 of these topics, and as to 13 others agreed only if Impax agreed to limitations as to the applicable time-period and/or scope. [Wyeth's Mot. Ex. 6.] Most surprising, however, was Wyeth's refusal to be deposed on any of five topics with which it agreed to move forward. Instead, Wyeth steadfastly contended that its objections and limitations as to every other topic must be conceded by Impax for the deposition to take place. [*E.g.*, *id.* Ex. 6, at 5.] This was unacceptable to Impax, and because Impax forewarned Wyeth that it would raise this issue with the Court during its conference on February 7th, Wyeth filed the instant motion the day prior.

D. By Contrast, Impax Has Moved Diligently In Responding To Wyeth's Discovery Requests, Such As Its Deposition Of An Impax Employee

On August 4, 2006—the same day Wyeth started to produce its NDA piece-meal—Impax produced the entirety of its Abbreviated New Drug Application ("ANDA"), which sets forth the key information regarding its drug formulations and testing thereof. [Ex. S.] Impax thereafter produced its lab notebooks, correspondence with the U.S. Food and Drug Administration ("FDA"), and other responsive documents on or before the Court's October 10th production deadline. Impax also timely responded to Wyeth's written discovery requests, including Wyeth's 64 substantive requests for admission. [D.I. 29.]

Impax also did not delay the deposition of Impax's fact witnesses in response to Wyeth's deposition tactics. On January 23, 2007—the day after Impax served its

Amended Notice—Wyeth noticed the deposition of Mark Shaw, REDACTED REDACTED to take place on February 9, 2007. [D.I. 73.] Impax agreed to make Mr. Shaw available on February 9th in his home district and the deposition took place less than a week after the date for which it was initially noticed.

IV. ARGUMENT

A. Impax's Notice Is Proper In Light Of The Disputed Issues In This Case.

1. Wyeth's restrictive view on a Rule 30(b)(6) deposition is inconsistent with the Federal Rules governing discovery

Wyeth's argument that Impax's Amended Notice is overbroad should be rejected. First, Wyeth manufactures an argument, with only a law review article in support, that Impax cannot require Wyeth to prepare a "super-human, omniscient witness." Wyeth's Mot., at 10. This straw-man argument is inconsistent with the plain text of Rule 30(b)(6), which does not require that a single witness be prepared to cover all issues. *See* Fed. R. Civ. P. 30(b)(6) ("the organization so named shall designate *one or more* officers, directors, or managing agents, or other persons who consent to testify on its behalf . . . .") (emphasis added). Moreover, Wyeth's restrictive interpretation is contrary to the law of the Third Circuit, where "it is well-recognized that the federal rules allow broad and liberal discovery." *Pacitti v. Macy's*, 193 F.3d 766, 777 (3d Cir. 1999) (internal citation omitted). Regardless of the discovery device employed, "the implied limit of discoverability in any discovery device is Fed. R. Civ. P. 26(b)(1)." *Alexander v. FBI*, 186 F.R.D. 137, 140 (D.D.C. 1998). With respect to Rule 30(b)(6) in particular, a sister court of the Third Circuit has stated:

> Federal Rule of Civil Procedure 26(b)(1) defines the scope of discovery "unless otherwise ordered by the court." I do not read Rule 30(b)(6) as carving out a special limitation on the scope of discovery defined in Rule 26(b)(1). Moreover, it is my view that Rule 26(b) does not permit such a special limitation. Indeed the language of Rule 26(b) provides that the only way to change the scope of discovery set forth in Rule 26(b)(1) is by order of the court "in accordance with these rules." It is therefore untenable to suggest that "describe with reasonable particularity the matters

> on which the examination is requested" is a limitation on the scope set forth in Rule 26(b)(1). It is inconsistent with the dictates of Rule 26(b).

Cabot Corp. v. Yamulla Enters., Inc., 194 F.R.D. 499, 500 (M.D. Pa. 2000) (internal citations omitted). Indeed, this Court very recently has held that, pursuant to Rule 26(b)(1), "discovery should ordinarily be allowed under the concept of relevancy unless it is clear that the information sought can have no possible bearing upon the subject matter of the action." *In re Intel Corp. Microprocessor Antitrust Litig.*, No. 05-1717-JJF, 2007 WL 137152, *5 (D. Del. Jan. 12, 2007) (quoting *La Chemise Lacoste v. Alligator Co.*, 60 F.R.D. 164, 171 (D. Del. 1973)). Thus, to the extent Wyeth argues that certain topics fall outside the specific allegations of the claims and defenses pled, this should be rejected because they all bear upon the subject matter of this action, which broadly include the validity and enforceability of the patents-in-suit. [*See also* D.I. 78.]

Upon closer review, a case cited in Wyeth's Motion on this point actually supports Impax. In *United States v. District Council of New York City*, No. 90-5722, 1992 WL 208284 (S.D.N.Y. Aug. 18, 1992), the witness, Agent Worsham, had already been deposed pursuant to Rule 30(b)(6). The issue before that court was whether Agent Worsham should be compelled to answer certain questions which she had refused to answer during her deposition. *See id.* at *2. The court denied defendant's motion to compel, noting that the questions implicated work product because Agent Worsham was assisting counsel and that "[t]he facts which defendants seek are available from first-hand sources, rather than investigators assisting counsel whose limited and selective knowledge is laced with work product protection." *Id.* at *14-*15. The case also shows that Impax's topic no. 33, which seeks the facts regarding Wyeth's Reply to Counterclaims, is particularly appropriate, because the plaintiffs in *District Council* did "not dispute that defendants [we]re entitled to discovery regarding the factual allegations in the Supplemental Complaint . . . [and had] permitted depositions of various F.B.I. agents." *Id.* at *3.

2. The Amended Notice's topics seek relevant evidence, and Wyeth's restrictions as to their scope are arbitrary and improper

Wyeth's objections and limitations to topic no. 3, which seeks the "formulation of EFFEXOR XR and the development thereof," is particularly illustrative of the impropriety of Wyeth's objections and limitations in general. Wyeth concedes that the subject matter of this topic is relevant, and thus is left to argue that "there is no reasonable way Wyeth could prepare a witness to marshal all of the facts necessary to properly address the sheer breadth of this topic." Wyeth's Mot., at 12. As noted above, this straw-man argument that one witness must be prepared for this topic is not consistent with the rule or case law. *See also Kanaji v. Phil. Child Guidance Ctr. of Children's Hosp.*, No. 00-937, 2001 WL 708898, *2 n.4 (E.D. Pa. June 20, 2001) ("a corporation cannot avoid designating a Rule 30(b)(6) deponent by claiming that no individual employee possesses specific knowledge of plaintiff's claims").

Wyeth also objects to the breadth of this topic, but as with any other discovery request:

> Rule 26(b)(2)(iii) provides five factors to help the Court determine whether the burden or expense of a discovery request is proportional to the needs of the case: . . . (A) the needs of the case, (B) the amount in controversy, (C) the parties' resources, (D) the importance of the issues at stake in the litigation, and (E) the importance of the proposed discovery in resolving the issues.

Hagemeyer N. Am., Inc. v. Gateway Data Sci. Corp., 222 F.R.D. 594, 600 (E.D. Wis. 2004) (internal quotation of Rule 26(b)(2)(iii) omitted). Thus, the Court should consider that Wyeth is the developer and seller of Effexor XR, which its purports to be "one of the world's most commercially successful drugs," and which it asserts to be an embodiment of the claims of the patents-in-suit, all of which it contends are non-obvious in light of the alleged commercial success of Effexor XR.

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In light of the time-period at issue, the

breadth of information as to Wyeth's development of Effexor XR during that time, how critical these facts are to the disputes regarding the invalidity and enforceability of the patents-at-issue, and Wyeth's injection of the development timeline into the case, surely Impax is entitled to proportional breadth in its deposition topic no. 3. *Cf. Hagemeyer*, 222 F.R.D. at 600. Moreover, REDACTED it surely can prepare one or more deponents on that development so that Impax can conduct discovery as to the same.

Notwithstanding that Wyeth has put at issue its work on Effexor XR going back to 1991, it now tries to curtail Impax's inquiry into development at Wyeth that took place after March 25, 1996—i.e., the filing date of its provisional patent application for the patents-in-suit. *See* Wyeth's Mot., at 5 (proposing narrowed topic no. 3).[1] This draconian date limitation must be rejected for at least two reasons.

First, there were continuation-in-part applications subsequent to the provisional application, but before the applications resulting in the patents-in-suit, that set forth new disclosures in their specifications. Impax contends that only these additional disclosures, not found in the provisional application, describe certain asserted claims such that REDACTED

Second, a patent applicant is under an obligation to apprise the U.S. Patent and Trademark Office ("PTO") of any new development that is material to patentability, up until the patent issues. The last of the three patents-in-suit—U.S. Patent No. 6,419,958—issued on July 16, 2002. Between 1996 and 2003, Wyeth submitted new filings with the

[1] Wyeth seeks the same time-frame limitation not only for the particular formulation that it currently markets as Effexor XR, but as to all of its venlafaxine extended release development. *See* Wyeth's Mot., at 5-6 (proposing that topic nos. 4-10 and 13-14 be limited to the period up to March 25, 1996). For the reasons discussed in the text, such a constraint is arbitrary and improper.

FDA regarding Effexor XR.[2] Testimony regarding any new information about Effexor XR that Wyeth disclosed to the FDA, but did not provide to the PTO during the patents' prosecution, is directly relevant, *inter alia*, to Impax's inequitable conduct defense.

Wyeth's arbitrary limitations as to other topics similarly should be rejected. Specifically, Wyeth also seeks to prevent deposition testimony concerning: (1) amendments to the NDA that were filed with the FDA after May 1996—narrowed topic no. 15; (2) advertising budgets, sales projections and profit margins for Effexor XR up to the second quarter of 2006—narrowed topic nos. 16 and 19-20; and (3) document collection procedures—narrowed topic no. 34. *See* Wyeth's Mot., at 7-9 & 14. As explained above, limiting this deposition (or any discovery) to only the information created before Wyeth's initial filing with the PTO is improper. The same conclusion applies as to its initial filing with the FDA because Wyeth's communications (or lack thereof) with that agency, including the timing of those communications, is highly relevant to the issues of claim priority and inequitable conduct. Testimony concerning advertising budgets, sales projections and profit margins for Effexor XR is relevant to the alleged commercial success of the claimed inventions. Similarly, because Wyeth is preparing to release a new anti-depressant drug related to Effexor XR—i.e., desvenlafaxine succinate [Ex. U]—any of Wyeth's devised strategies to transition the market from Effexor XR to desvenlafaxine may establish whether Effexor XR's sales are due to marketing efforts or the patented inventions. Finally, the development and testing of Effexor XR occurred around the world, and accordingly Wyeth made statements to the Court that all relevant documentation from foreign sources were collected. [D.I. 41, at 3 ("Wyeth has already gone to great lengths to collect over 1.3 million pages from numerous U.S. and foreign facilities.").] Impax is entitled to obtain testimony about the extent of this document collection.

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[2] Despite agreeing to do so [Ex. T, Resp. to Req. for Prod. Nos. 48-49, 51], Wyeth has not produced its correspondence with the FDA regarding Effexor XR between from the initial filing of its NDA to 2003, when it commenced the *Teva* litigation.

3. Wyeth's objections as to the over-breadth of certain topics should be overruled

As set forth below, Wyeth's parallel arguments as to the other topics that it contends are overbroad are similarly inapt:

- Topic no. 27 seeks testimony on comparisons performed between the chemical properties of propranolol and venlafaxine. The patents-in-suit disclose in their specification that "[i]t was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble." [D.I. 1 Ex. A col. 4:57-60.] Moreover, during their prosecution, Wyeth's patent claims were amended to overcome a rejection of obviousness in view of a patent disclosing a propranolol extended release formulation using the same excipients and manufacturing processes as the disclosures of the patents-in-suit. [Ex. V.] Moreover, Wyeth had a propranolol extended release formulation in the marketplace—called Inderal® LA—at the time the provisional application for the patents-in-suit was filed. As such, comparisons between the two chemicals and their extended release formulations are known to Wyeth, and are directly pertinent to understanding the scope of the invention at issue.
- Topic no. 18 seeks results of market research conducted by, or on behalf of, Wyeth regarding the treatment of the signs and symptoms of persons suffering from major depressive disorder. Some of the asserted claims are directed to methods "for providing *therapeutic* blood plasma concentration of venlafaxine," "eliminating the troughs and peaks of drug concentration in a patients [sic] blood plasma level attending the *therapeutic* metabolism of . . . venlafaxine." [D.I. 1 Ex. A col. 12:63-14:22 (emphasis added).] Topic no. 18 tracks these claims because it seeks testimony on market research as to these therapeutic aspects of the claimed invention. This is relevant, *inter alia*, to (1) assessing a need for the patented invention and its alleged commercial success, which are two important factors in obviousness analysis, and (2) determining whether Wyeth obtained new data during the prosecution of the patents-in-suit showing that the claimed therapeutic properties of its extended release formulation were not in fact achieved in patients, but then failed to apprise the PTO of the same.
- Topic no. 17, which seeks the "causes in any fluctuations of, and strategies to maintain or increase the market share of Effexor XR," is relevant for demonstrating that Effexor ER's commercial success is unrelated to the patented invention—a critical factor in an obviousness analysis. In addition, topic no. 20, which seeks testimony on the content and effectiveness of any advertising and promotional efforts is important for the same reason—i.e., to assess whether the commercial success of Effexor XR is related to the patented invention or to advertising and promotional efforts.
- For topic no. 33, which seeks the facts and documents supporting the denials and affirmative statements in Wyeth's Reply to Counterclaims, Wyeth again argues that it cannot produce a single witness to answer all the facts regarding these denials and statements, even though there is no requirement that Wyeth produce a single witness. *See* Part IV.A.1, *supra*. There is no legitimate basis for refusing to produce one or more witnesses on this topic.

- For topics no. 29, 31, 25 and 26, Wyeth objects to "Wyeth's awareness" and "Wyeth's knowledge" as being vague and ambiguous. However, documents and transcripts from the *Teva* litigation demonstrate some awareness and knowledge by Wyeth of the subject matters of these topics. Impax now seeks the full extent to which Wyeth was aware of these topics. Indeed, it is likely that a very limited set of persons and documents capture Wyeth's knowledge and awareness of the two articles about one clinical study of Effexor XR, and on the development work on an extended release venlafaxine formulation by Alza, which are the subjects of these topics. That many people may know duplicative bits and pieces of information does not obviate the requirement that Wyeth take reasonable steps to produce an informed witness.

4. Impax's noticed topics are reasonably particularized

Wyeth's argument as to lack of particularity in the noticed topics should also be rejected. First, "reasonable particularity" of the deposition topics does not define the scope of the deposition because Rule 26(b)(1), not a Rule 30(b)(6) notice, determines the scope of deposition. Second, Impax has set forth the deposition topics with sufficient particularity for Wyeth to identify and prepare the appropriate witness(es). For example, in *Alexander v. FBI*, 186 F.R.D. 137 (D.D.C. 1998), the court found the noticed topic "the computer systems commonly known as or referred to as 'Big Brother' and/or 'WHODB'" to be sufficiently particular, and in doing so explained:

> plaintiffs specifically stated that they wanted testimony on the WhoDB . . . . Both parties are well aware of the discoverable issues in this case (whether they choose to abide by them or not). Defendant EOP was on sufficient notice of what discoverable matters the plaintiffs would inquire into on the WhoDB deposition.

Id. at 140. Likewise, topics such as "formulation and development of Effexor XR" provide sufficient notice to Wyeth as to what discoverable matters Impax would inquire into given that, like in *Alexander*, the parties in this case are also "well aware of the discoverable issues."[3]

[3] By contrast, *Reed v. Bennet*, 193 F.R.D. 689 (D. Kan. 2000) cited by Wyeth, is inapt. In *Reed*, the court found a Rule 30(b)(6) notice overbroad because the noticing party had indicated that the listed topic areas were not exclusive. *See id.* at 692. Impax's Amended Notice, however, seeks testimony only as to the topics listed therein.

5. In light of discovery in this case and in the *Teva* litigation, Impax's Amended Notice is not duplicative

Omitted from Wyeth's Motion is the fact that Teva did not explore several areas of testimony that Impax wishes to pursue. One example is the defense of inequitable conduct, which Teva was not permitted to assert because it sought to amend its answer and counterclaims near the close of discovery. [Ex. W.] Because many of the topics seek discovery as to claims and defenses that Teva could not pursue, Wyeth's fear of duplication is a non-starter.

Moreover, the fact that Wyeth has produced transcripts of depositions from the *Teva* litigation does not preclude Impax from conducting depositions of some of the same individuals, or on some overlapping subjects, in this case. Wyeth cites no case law that stands for such a proposition (*see* Wyeth's Mot., at 20), while Impax had found case law to the contrary. *See, e.g.*, *SmithKline Beecham Corp. v. Apotex Corp.*, No. 99-CV-4304, 2004 WL 739959, *4 n.6 (E.D. Pa. Mar. 23, 2004).[4] Impax is entitled to its day in court, a basic tenet of American jurisprudence. Even on topics explored in part by Teva, Impax is entitled to pursue and follow-up as it sees fit. It also quite telling that Wyeth contends that the prior deposition testimony is sufficient for Impax's defense, when Impax's review of the same testimony enabled it to identify the specific areas for which corporate testimony is needed because of witnesses' inability to recollect key facts or because counsel improperly prevented the witness from responding. Just a few of the many examples of these are:

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[4] In *SmithKline*, the court permitted a Rule 30(b)(6) deposition to go forward on a topic previously litigated by the patentee (SmithKline) with another accused infringer in another case, stating:

> We also reject SmithKline's argument that it should not have to prepare a witness to testify on Category 5 because it already produced to Alphapharm information regarding seeding generated during other litigation. SmithKline has not convinced the Court that the information it already produced to Alphapharm eliminates the need for a deposition on Category 5.

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Accordingly, the Court should not be lulled by Wyeth's repeated mantra of "already done in the *Teva* litigation" so as to deny Impax an opportunity obtain discovery so as to defend itself.

B. Impax's Amended Notice Does Not Seek Contention Discovery

Wyeth repeatedly uses the moniker of "contention discovery" as to Impax's deposition topics, and points to a smattering of cases and citations to hearings before other judges of this Court, to highlight the uncontroversial proposition that contention discovery is best left to interrogatories. *See* Wyeth's Mot., at 15-17. Courts have previously cut through these types of tactics to allow Rule 30(b)(6) topics focused on the facts in a party's possession. Wyeth's rhetoric as to the Court's disdain for "contention depositions" is particularly inapt, because "[w]hether a Rule 30(b)(6) deposition or a Rule 33(c) contention interrogatory is more appropriate will be a case by case factual determination." *U.S. v. Taylor*, 166 F.R.D. 356, 363 n.7 (M.D.N.C. 1996). An opinion by a sister court of the Third Circuit on the very issue, in the context of a Hatch-Waxman patent infringement case, is particularly instructive. In *SmithKline*, the court parsed through the noticed deposition topics of Alphapharm, an accused infringer, to determine which were in fact seeking legal contentions and which were seeking testimony regarding facts in the possession of SmithKline, the patentee. The court stated:

> Category 1 of Alphapharm's deposition notice calls for testimony regarding "[t]he conditions under which particular forms of paroxetine, including without limitation paroxetine hydrochloride anhydrate, allegedly

> convert to paroxetine hydrochloride hemihydrate ." [ ] SmithKline prepared a witness to testify on this subject and that witness testified at length about the various ways in which paroxetine hydrochloride anhydrate can convert to paroxetine hydrochloride hemihydrate. However, SmithKline's witness was not prepared to testify about the conditions under which this conversion can occur inside the human body.
>
> According to Alphapharm, SmithKline has taken the position that paroxetine hydrochloride can convert to a different form inside the body, and has publicly alleged infringement of its patents based on in vivo conversion. [ ] SmithKline does not dispute this assertion. *However, SmithKline claims that questions about in vivo conversion of paroxetine hydrochloride require expert testimony, and that such testimony is premature. We disagree. If SmithKline has concluded that its patents are infringed when paroxetine hydrochloride converts to a different form inside the body, it must have some basis for that belief, and Alphapharm is entitled to discover that information.* [ ] Accordingly, SmithKline is ordered to prepare a witness to testify to the matters described in Category 1.

SmithKline, 2004 WL 739959 at *4 (emphasis added and internal citations omitted). Indeed, the patentee in that case conceded that many of the categories were proper for Rule 30(b)(6) deposition *per se*, and prepared a witness to testify as to those topics, but not to the point of providing its legal positions. *See id.* at *1-4. The only topic that on its face was considered to be wholly better suited for contention interrogatories was "[t]he bases for [SmithKline's] allegations in its complaints filed in these consolidated actions that Alphapharm infringes and will infringe the patents asserted in those complaints." *Id.* at *4 (bracketed text in original). Thus, courts have distinguished between legal contentions drawn directly to infringement, invalidity, and enforceability, on the one hand, and topics drawn to the relevant facts that underlie those contentions, which are appropriate for deposition, on the other. *See, e.g., Medtronic Xomed, Inc. v. Gyrus ENT LLC*, No. 304CV400J32, 2006 WL 786425, *1 (M.D. Fla. Mar. 27, 2006).[5]

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[5] In *Medtronic*, the court stated (citations to record omitted, bracketed text in original):

> Defendant previously filed a motion to compel Plaintiff to designate a corporate representative to testify on various specific topics, one of which focused on "prior art relevant to the validity / invalidity of the 957 Patent." [ ] Despite Plaintiff's objection that such information would be more appropriately addressed through expert testimony, the Court granted

(Footnote continued)

In this case, Wyeth asserts that topic no. 1, which seeks information on the conception and reduction to practice of the claimed inventions, amounts to contention discovery. *See* Wyeth's Mot., at 15. However, conception and reduction to practice are events that took place within Wyeth, and thus Wyeth must have knowledge as to the facts pertaining to those events. For example, in response to Impax's interrogatories, Wyeth contends that REDACTED REDACTED This should not preclude Impax from ascertaining what actually transpired on REDACTED who was present, what was discussed, was this considered significant at the time, and why. Wyeth's contention is merely the basis for the inquiry as to the underlying facts that support the contentions, and Impax is entitled to take Wyeth's deposition on the latter.

In yet another attempt to avoid testimony as to topic no. 33 regarding Wyeth's Reply to Counterclaims, Wyeth calls it "contention discovery" and adds a work product objection. *See* Wyeth's Mot., at 15-19. However, given the particulars of the pleading, this topic does not seek contentions nor any fact to which an immunity attaches. To the contrary, it seeks testimony pertaining to the affirmative facts stated in Wyeth's responsive pleading, and the denials of the facts alleged in Impax's counterclaim of inequitable conduct, pursuant to Rule 9(b). Examples of factual statements made in Wyeth's Reply to Counterclaims are:

- Wyeth also admits that after undergoing a lengthy, costly, and uncertain research and development process to obtain FDA approval, Wyeth began selling an immediate release dosage form of venlafaxine hydrochloride under the brand name Effexor® in 1994 in the United States. Wyeth, however, recognized the shortcomings of immediate release Effexor® early on, and began working towards possible solutions to those shortcomings with the development of an extended release product even before the immediate release Effexor® product was ever approved or sold. After undergoing yet another lengthy, costly, and uncertain research and development process to obtain FDA approval for the extended release dosage form of venlafaxine hydrochloride that it developed, Wyeth began selling an extended release dosage form of venlafaxine

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Defendant's motion to compel in part and opined that the "factual evidence requested [with respect to prior art] is discoverable through a Fed. R. Civ. P. 30(b)(6) deposition."

hydrochloride under the brand name Effexor® XR in 1997 in the United States. Wyeth further admits that it still sells immediate release venlafaxine hydrochloride under the brand name Effexor® for the treatment of depression in the United States, but states that the sales Effexor® are but a small fraction of the sales of Effexor® XR.

- Wyeth denies the allegations of paragraph 66 of Impax's Amended Counterclaims. Responding further, Wyeth denies Impax's allegation that "the only study directly comparing the two formulations did not show the claimed statistical significance." Wyeth further states that during the prosecution of the patents-in-suit, Wyeth never represented to the PTO that each clinical study, standing alone, established a statistically significant improvement of Effexor® XR over immediate release Effexor®.

[D.I. 46 ¶¶ 7 & 18.] Because topic no. 33 is directed to the facts asserted and denied by Wyeth, its objection as to work product is misplaced, especially as to events that took place prior to the issuance of the patents-in-suit. *See* IV.C.1, *infra*.

C. The Noticed Topics Seek Highly Relevant Non-Privileged Information

1. Wyeth's assertion of attorney work product is misplaced

In its motion, Wyeth vaguely asserts that "[b]ecause the requested discovery is so intertwined with issues of attorney-client privilege and/or work product immunity, it is best conducted through means other than a Rule 30(b)(6) deposition." Wyeth's Mot., at 22. To the extent Wyeth asserts attorney work product immunity as a basis to prevent its deposition as to the prosecution of the patents-at-issue (topic nos. 21-24, 28-29, 31 and 33), it is inapplicable and should be rejected. The work-product doctrine protects from discovery the materials "prepared in anticipation of litigation." Fed. R. Civ. P. 26(b)(3). "It is well-established that the party asserting work-product protection has the burden of proving that the materials were prepared in anticipation of litigation." *SmithKline Beecham Corp. v. Apotex Corp.*, 232 F.R.D. 467, 473 (E.D. Pa. 2005) (citing *Holmes v. Pension Plan of Bethlehem Steel Corp.*, 213 F.3d 124, 138 (3d Cir. 2000)). As such,

> work performed by an attorney to prepare and prosecute a patent application does not fall within the parameters of the work-product protection . . . since the prosecution of [a] patent application is a non-adversarial, *ex parte* proceeding. Thus, work done to that end is not "in anticipation of" or "concerning" litigation.

In re Minebea Co., 143 F.R.D. 494, 499 (S.D.N.Y. 1992) (internal citations omitted); *see also Beasley v. Avery Dennison Corp.*, No. 04-0866, 2006 WL 2854396, *3 (W.D. Tex.

Oct. 4, 2006) ("the work product immunity does not apply if the primary concern is with claims raised in the *ex parte* patent application prosecution"). Here, Wyeth has not shown—because it cannot show—that any of the prosecution of the patents-in-suit (much less all of it) was done with an eye on litigation that commenced three years after the issuance of the last patent.

2. Wyeth is incorrect in its assertion that the intent in making the statements of the patents-at-issue is irrelevant, because inequitable conduct requires the showing of an intent to deceive

To avoid a potentially unpleasant deposition on its intent in drafting the very wording of the patents-at-issue, Wyeth asserts inapposite law regarding claim construction from the Federal Circuit's *Markman* opinion. *See* Wyeth's Mot., at 22. Impax's topic nos. 21-23 and 28, regarding the intended meanings of phases or claims of the patents-at-issue and the patent attorney's arguments made in their prosecution, are directed to obtaining discoverable information relevant to Impax's counterclaims of inequitable conduct and patent misuse. For example, inequitable conduct involves "failure to disclose information material to patentability, coupled with an intent to deceive or mislead the PTO." *Bruno Indep. Living Aids v. Acorn Mobility Servs.*, 394 F.3d 1348, 1351 (Fed. Cir. 2005) (upholding a finding of inequitable conduct where the patent prosecuting attorney withheld prior art from the PTO that the patentee concurrently disclosed to the FDA during patent prosecution). "Intent need not, and rarely can, be proven by direct evidence. [] Rather, in the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *Id.* at 1354 (emphasis added, internal citation omitted). In light of the need for inferential evidence, "the defense of inequitable conduct makes the attorney's mental impressions during the patent prosecution proceedings directly at issue in the litigation." *Resqnet.Com, Inc. v. Lansa, Inc.*, 2004 WL 1627170, *6 (S.D.N.Y. Jul. 21, 2004) (citing *Environ Prods. Inc. v. Total Containment, Inc.*, 41 U.S.P.Q.2d 1302, 1306 (E.D. Pa. 1996)). Thus, Impax's topics directed to the "intended meanings" of certain statements in

the patents and the prosecution history are directed to eliciting highly relevant testimony.[6]

3. Wyeth's assertion of privilege is overbroad and seeks to block non-privileged information relevant to Impax's inequitable conduct and other claims and defenses

Wyeth's assertion of privilege in this case mirrors its improper conduct in the *Teva* litigation—i.e., using privilege to shield not only the attorney-client communication, but any facts that speak to whether a communication took place. Information is privileged only if: (1) it is or it is based on confidential information; (2) it is communicated by the client to an attorney; and (3) it is communicated in order to obtain legal counseling. *See In re Spalding Sports Worldwide*, 203 F.3d 800, 805 (Fed. Cir. Feb. 11, 2000). In light of these guidelines, courts have refused to find privilege if either the communicated information was not confidential and/or if it was communicated for business reasons rather than to seek legal advice. Examples of patent prosecution related information that have been found not to be privileged include:

- Name and address of the sender or recipient provided in the cover letters to faxes and interoffice memoranda;
- Authorization from client to file a patent application or a continuing patent application without more;
- Letter from attorney informing client about the expiration of the period for filing an European patent application;
- Attorney's notification to client that a patent is about to issue; and
- Letters between attorney and client discussing anticipated cost of translating patents and pursuing patent applications.

Softview Comp. Prods. Corp. v. Haworth, Inc., No. 97-8815, 2000 WL 351411 at *9-*11

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[6] To the extent Wyeth in its reply claims that Impax is free to take the individuals' depositions in this regard, Impax notes that Wyeth has identified REDACTED [Ex. J, Resp. to Interrog. No. 4.] Thus, Impax needs to conduct a deposition of Wyeth to ascertain REDACTED Moreover, Impax has offered to REDACTED if the same is designated and prepared to testify on the relevant patent prosecution topics. [Ex. R.] This would prevent the issue of the witnesses' failure to recall relevant information due to lack of proper preparation, while at the same time reducing inconvenience to Wyeth.

(S.D.N.Y. Mar. 31, 2000). As one court explained:

> [T]hese letters merely address (1) the order and sequencing of the work loads; (2) an evaluation of the importance of the subject matter; and (3) possible additional patent filings. These purely administrative matters are not the type of communications which the cloak of the attorney-client privilege is intended to protect. *See In re Witnesses Before Special March 1980 Grand Jury*, 729 F.2d 489, 491-92 (7th Cir. 1984) (citing *Fisher v. United States*, 425 U.S. 391, 40 (1976) (privilege only protects disclosures necessary to obtain informed legal advice)). A client's instructions regarding the relative importance of a patent's prosecution and the client's authorization to file patent applications are simply not privileged communications. *See id.* They are administrative business matters unrelated to legal advice.

Ami/Rec-Pro Inc. v. Ill. Tool Works, Inc., 46 U.S.P.Q.2d 1369, 1371 (N.D. Ill. 1998). Thus, a vital inquiry in determining privilege is "whether the communication was made by a client to an attorney for the purpose of obtaining legal advice." *In re Spalding*, 203 F.3d at 805. This inquiry is particularly critical in the context of technical information known to a patent attorney. This is because:

> not all technical facts in the possession of a patent attorney are automatically treated as implicit requests for legal advice, or as part of a dialogue between attorney and client concerning the proper scope of the claim. Rather, courts require at least some evidence or indicia that the technical facts were (1) communicated to the attorney by the client (2) as part of a dialogue concerning the proper scope of the claim.

Ami/Rec-Pro, 46 U.S.P.Q.2d at 1372 (internal citation omitted).

Indeed, at least one court since *In re Spalding* has refused to grant privileged status to technical documents sent to patent departments. *See McCook Metals v. Alcoa, Inc.*, 192 F.R.D. 242, 255 (N.D. Ill. Mar. 2, 2000) ("These documents are technical drawings and sketches, tables and test results produced from the inventors and engineering departments and sent to the patent departments. Some are attachments to letters to in-house patent attorneys in response to a request for information, while others are freestanding. The document themselves contain no request for legal advice, nor is any given, and thus fall outside the ambit of the privilege.") (citation omitted).

Moreover, even if a communication is found to be privileged, the privilege extends only to the communication, not to the facts underlying the communication:

> The protection of the privilege extends only to communications and not to facts. A fact is one thing and a communication concerning that fact is an entirely different thing. The client cannot be compelled to answer the question, 'What did you say or write to the attorney?' but may not refuse to disclose any relevant fact within his knowledge merely because he incorporated a statement of such fact into his communication to his attorney.

Upjohn Co. v. U.S., 449 U.S. 383, 395-96 (1981) (citation omitted). By analogy, the facts underlying a party's decision not to disclose prior art during patent prosecution have been found to be discoverable. *See Martin Marietta Materials, Inc. v. Bedford Reinforced Plastics, Inc.*, 227 F.R.D. 383, 394 (W.D. Pa. 2005) ("the underlying facts supporting the Plaintiff's decision not to disclose prior art during the application process is not protected under the attorney-client privilege").

Finally, "lawyer-authored communications are covered by the privilege only if they reveal the client's confidences." *Ami/Rec-Pro*, 46 U.S.P.Q.2d at 1371 (internal citation omitted). In other words, information known to an attorney independent of communications with the client is not protected. This is because typically there is no anticipation of litigation when patents were prosecuted and therefore there is no "work product" protection. *See* Part IV.C.1, *supra*. Examples of information known to an attorney that have been ordered to be disclosed include:

- Information in attorney's memorandum of conference with a patent examiner which contains no confidential information;
- Attorney's status report regarding patent application which does not reveal client confidences or legal analysis;
- Attorney's handwritten notes of a conference which does not reveal client confidences or legal analysis; and
- Patent search report conducted by third party which does not reveal confidential information imparted by client to counsel.

Softview, 2000 WL 351411 at *9-*11.

In light of the above contours, Wyeth's claim of privilege cannot extend over the entirety of the topics in the realm of patent prosecution. Indeed, topic no. 24, which seeks "Wyeth's standard practices and policies from 1990 to the present with respect to the prosecution of U.S. patent applications," does not seek any privileged information because

it pertains to Wyeth's practices and policies, and not any particular communication between Wyeth or the named inventors and their patent attorneys.[7] Despite this, Wyeth's counsel repeatedly blocked an entire line of questioning of a patent inventor on this very same topic, by asserting privilege, in the *Teva* litigation. [Ex. P, at 60:2-90:4.].

REDACTED

Ironically, Wyeth now points to this Rule 30(b)(6) deposition testimony, as somehow precluding an unrelated defendant, Impax, from seeking additional discovery on the same topic. *See* Wyeth's Mot., at 20.

As to Impax's other topics directed to Wyeth's invention records that underlie the patents-in-suit (no. 2), the basis for specific statements in the patents-in-suit and prosecution document (nos. 22-23, 28), and prosecutor's knowledge of certain articles regarding relevant clinical studies (nos. 29, 31), at the very least Impax is entitled to ascertain if there is any non-privileged information—e.g., the attorney drafting the prosecution document or parts thereof without client consultation; the patent attorney conducting prior art searches without client consultation; the patent attorney physically obtaining prior art or the articles at issue—and who has knowledge of pertinent information regardless of privilege, when any privileged communications did occur, between whom, and whether this was transmitted in writing or otherwise. None of this information falls within the properly defined scope of privilege, and Wyeth should not be allowed to use an oversized cloak of privilege to hide this non-privileged and relevant information.

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[7] Wyeth also mischaracterizes this topic in asserting that it is overbroad. *See* Wyeth's Mot., at 21 n.4. The time-period is intended to capture practices and policies in place from REDACTED Moreover, the practices and policies are exactly the type of inferential evidence of inequitable conduct that Impax must be allowed to pursue in light of more direct evidence—actual attorney-client communications—being subject to privilege. *Cf. Bruno*, 394 F.3d at 1354.

4. That privileged and non-privileged subject matter are "intertwined" is not a proper ground to prevent a deposition

Impax further notes that Wyeth's attempt to require Impax to pursue other means of discovery when privilege is implicated is without legal support. The party asserting privilege bears the burden proving that privilege applies to the information at issue. *In re Grand Jury etc.*, 603 F.2d 469, 474 (3d Cir. 1979). A blanket assertion of privilege is insufficient. Rather, privilege is "determined on a case-by-case basis." *In re Spalding*, 203 F.3d at 805. As the Third Circuit explained, "privilege obstructs the search for truth and because its benefits are, at best 'indirect and speculative,' it must be strictly confined within the narrowest possible limits consistent with the logic of its principle." *In re Grand Jury Investigation*, 599 F.2d 1224, 1235 (3d Cir. 1979). Thus, deposition is really the best means to define the contours of the privilege, once asserted, by ascertaining the underlying facts in support of that assertion once made. Wyeth's counsel also may raise concerns about being required "to continually make instant judgment calls on matters of privilege and work product immunity, with the risk of inadvertent waiver looming." [Wyeth's Mot. Ex. 6, at 5.] In light of governing case law, however, Impax should not be prevented from obtaining relevant, non-privileged, information based on counsel's fears and speculations.[8]

D. Wyeth's Efforts To Delay Discovery Should Not Be Countenanced

Wyeth's Motion and refusal to commence its deposition on any topic is an attempt to delay Impax's discovery of relevant facts in the hopes that it forces Impax into seeking additional time to conduct discovery. *See* Part III, *supra*. To prevent this result, Impax seeks a ruling from the Court, either prior to the scheduled hearing of the instant motion, or at the hearing itself, that the parties must proceed in March with those deposition topics

[8] Moreover, Impax is willing to enter into a mutual stipulation that neither party will assert waiver of privilege in light of any testimony until the 30-day period for confidentiality designations under the Stipulated Protective Order [D.I. 84] has passed, thus giving counsel an opportunity to review, and retract or reach another understanding as to how to treat any problematic testimony.

for which Wyeth has agreed to provide a witness. To the extent Wyeth argues in reply that it should not be made to prepare witnesses for certain topics, when it may be required to prepare the same or other witnesses to testify to additional topics later, Wyeth's complaint should fall on deaf ears. Wyeth has chosen to seek a protective order on 29 of 34 topics, and must face the consequences objecting to, and seeking to limit, so many topics narrowly drawn to relevant and discoverable information.

V. CONCLUSION

For the foregoing reasons, Wyeth's Motion should be denied and the Court should order that Wyeth's Rule 30(b)(6) deposition commence in March 2007.

RICHARD K. HERRMANN (I.D. No. 405)
MARY B. MATTERER (I.D. No. 2696)
MORRIS JAMES LLP
500 Delaware Avenue, 15th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800
rherrmann@morrisjames.com

M. PATRICIA THAYER (*pro hac vice*)
JOHN M. BENASSI (*pro hac vice*)
JESSICA R. WOLFF (*pro hac vice*)
DANIEL N. KASSABIAN (*pro hac vice*)
SAMUEL F. ERNST (*pro hac vice*)
HELLER EHRMAN LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92101
Telephone: (858) 450-8400
Facsimile: (858) 450-8499

Attorneys for IMPAX LABORATORIES, INC.

Dated: February 21, 2007

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No.: 06-222 JJF

DEFENDANT'S IMPAX LABORATORIES, INC.'S

FIRST SET OF REQUESTS FOR PRODUCTION (NOS. 1-3)

Pursuant to Federal Rule of Civil Procedure 34, Defendant IMPAX Laboratories, Inc. ("IMPAX" of "Defendant"), by its counsel, directs the following Requests for Production to Plaintiff Wyeth ("WYETH" or "Plaintiff") to produce all documents and things requested herein at the offices of Heller Ehrman LLP, 333 Bush Street, San Francisco, California, 94104, within 33 days of the date of service hereof.

When used in the following requests for production, the following definitions apply:

1. "WYETH" means Plaintiff Wyeth and that company as it was previously named and any related companies, divisions, or subsidiaries, past or present, and the past or present directors, officers, employees, agents, or attorneys thereof, including but not limited to foreign subsidiaries and divisions.

2. "AND/OR": As used herein, the conjunctions "and" and "or" shall be interpreted conjunctively and shall not be interpreted to exclude any information otherwise within the scope of the request.

3. DATE means the exact day, month, AND year, if so ascertainable, OR if not, the best approximation (including relationship to other events).

4. "DOCUMENT" or "DOCUMENTS" means all written, printed, typed, electronically produced, electronically stored, photostatic, photographed, recorded, OR otherwise reproduced communications OR records of every kind AND description, whether comprised of letters, words, pictures, sounds, symbols, OR combinations thereof. DOCUMENTS include originals as well as drafts, copies, marked-up copies, non-identical duplicates, AND computer files, including backup OR archival copies. DOCUMENTS include DOCUMENTS created AND/OR received by WYETH AND/OR by any of WYETH'S consultants, agents, AND/OR any other PERSON OR PERSONS.

5. "PERSON" refers to any natural person, firm, association, organization, partnership, business, trust, corporation, OR public entity.

6. "IDENTIFY" used with respect to a DOCUMENT means to provide: the kind of DOCUMENT (*e.g.*, letter, memo, etc.); the title OR name by which the DOCUMENT is referred to; the DATE of the DOCUMENT; the identity of its author OR the PERSON creating the DOCUMENT; the identity of each PERSON to whom the DOCUMENT was addressed, sent, OR copied; the present location of the original AND all copies thereof; the name of the custodian of the DOCUMENT; AND a general description of the subject matter.

7. "IDENTIFY" used with respect to a PERSON, means to state:

(a) His, her, OR its full name AND all known business OR other addresses AND telephone numbers;

(b) If a natural PERSON, his or her last known residence address AND telephone number; AND

(c) Such PERSON'S relationship to YOU.

8. "IDENTIFY" used in reference to an act, instance, transaction, occasion, oral discussion, conversation, COMMUNICATION, OR event, means to state the DATE

upon which AND the location at which it occurred, the identity of each PERSON who participated therein OR who was present when it occurred, its substance (*i.e.* what was said AND by whom AND/OR what transpired) AND the identity of each DOCUMENT, which, in whole OR in part, was the subject of the act OR in which it is manifested, referred to OR expressed.

INSTRUCTIONS

1. Each request below extends to any DOCUMENTS and things in the possession, custody OR control of WYETH. The DOCUMENT is deemed to be in WYETH'S possession, custody OR control, if it is in WYETH'S physical custody, OR if it is in the physical custody of any other PERSON and WYETH (a) owns such DOCUMENTS in whole OR in part; (b) has a right by contract, statute OR otherwise to use, inspect, examine OR copy such DOCUMENTS on any terms; (c) has an understanding, express OR implied, that WYETH may use, inspect, examine OR copy such DOCUMENTS on any terms; OR (d) has, as a practical matter, been able to use, inspect, examine OR copy such DOCUMENTS when WYETH has sought to do so. Such DOCUMENTS shall include, without limitation, DOCUMENTS that are in the custody of WYETH'S attorneys OR other agents.

2. Unless otherwise stated, the time period covered by this notice is up to AND including the DATE on which the DOCUMENTS are produced.

3. Pursuant to rule 26(e) of the Federal Rules of Civil Procedure, these requests for production of DOCUMENTS and things are deemed continuing to the fullest extent permissible AND to apply to all DOCUMENTS that WYETH subsequently creates, develops, discovers OR receives.

4. If WYETH cannot respond to any request in full, it should respond to the fullest extent possible, explain why it cannot respond to the remainder, AND describe the nature of the DOCUMENTS that it cannot furnish.

5. It is not intended that this notice require the disclosure of any DOCUMENTS that are privileged. For any DOCUMENTS and things withheld on such grounds, OR any other grounds, please provide a written response with the following information:

(a) A description of the DOCUMENT sufficiently particular to IDENTIFY it for purposes of a court order;

(b) The DATE of the DOCUMENT;

(c) The nature of the protection claimed;

(d) A list of all PERSONS who participated in the preparation of the DOCUMENT;

(e) A list of all PERSONS who have received OR reviewed copies of the DOCUMENT; AND

(f) A list of all PERSONS to whom the DOCUMENT was circulated, OR its contents communicated.

REQUESTS FOR PRODUCTION

REQUEST NO. 1:

All DOCUMENTS and things produced and in discovery by WYETH in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey.

REQUEST NO. 2:

All DOCUMENTS related to requests for production propounded by Teva Pharmaceutical Industries Ltd. in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, including but not limited to requests for production, responses and objections to requests for production, meet and confer

letters regarding requests for production, and other correspondence regarding requests for production.

REQUEST NO. 3:

All transcripts of hearings AND depositions conducted in connection with *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, with those portions of the transcripts redacted that were designated as confidential by Defendant Teva Pharmaceuticals USA, Inc. AND/OR Teva Pharmaceutical Industries Ltd.

REQUEST NO. 4:

All DOCUMENTS, including but not limited to exhibits, presentations, and demonstratives, introduced or used at hearings AND depositions conducted in connection with *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, with those portions of the DOCUMENTS redacted that were designated as confidential by Defendant Teva Pharmaceuticals USA, Inc. AND/OR Teva Pharmaceutical Industries Ltd.

Dated: June 23, 2006

M. PATRICIA THAYER (*pro hac vice*)
JOHN M. BENASSI (*pro hac vice*)
JESSICA R. WOLFF (*pro hac vice*)
HELLER EHRMAN LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92101
Telephone: (858) 450-8400
Facsimile: (858) 450-8499

MARY B. MATTERER (I.D. No. 2696)
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Ave., 10th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800

Attorneys for Defendant IMPAX LABORATORIES, INC.

CERTIFICATE OF SERVICE

I, Francesca Romero, declare:

I am over 18 years of age and a party to this action. I am a resident of the County of San Diego, State of California. My business address is: 4350 La Jolla Village Drive, San Diego, California 92122.

On June 23, 2006, I served the following document:

DEFENDANT'S IMPAX LABORATORIES, INC.'S FIRST SET OF REQUESTS FOR PRODUCTION (NOS. 1-3)

upon counsel of record listed below by email transmission and U.S. Mail:

Jack B. Blumenfeld
Melissa S. Myers
Morris, Nichols, Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
Tel: (302) 658-9200
Fax: (302) 658-3989

Attorneys for Plaintiff
WYETH

Basil J. Lewris
Linda A. Wadler
Finnegan, Henderson, Farabow,
Garrett & Dunner L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001
Tel: (202) 408-4000
Fax: (202) 408-4400

Attorneys for Plaintiff
WYETH

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 23rd day of June, 2006, at San Diego, California.

Francesca Romero

SD 820415 v1

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	C. A. No. 06-222 (JJF)

PLAINTIFF'S RESPONSES AND OBJECTIONS TO IMPAX'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-4)

Plaintiff, Wyeth, hereby responds to the First Request for Production of Documents and Things (Nos. 1-4) served by Defendant Impax Laboratories, Inc. (hereinafter "Impax") on June 23, 2006 via e-mail transmission and U.S. mail.

GENERAL OBJECTIONS

1. Wyeth objects to any request to the extent it seeks to impose on Wyeth any obligation not required by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the District of Delaware.

2. Wyeth objects generally to the production of documents and things protected by the attorney-client privilege, work product immunity or any other applicable privilege. To the extent that such documents and things not otherwise objectionable are called for by Impax's requests, they will be identified in a listing of withheld documents which will be prepared in due course and exchanged with Impax on a mutually agreed upon date.

Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list.

11. Wyeth objects to the production of documents and things subject to the rights of third parties not affiliated with Wyeth. In addition, Wyeth objects to the production of non-Wyeth documents or information subject to a protective order entered in a litigation other than the above-captioned litigation.

12. Wyeth objects to Impax's definition of the term "Wyeth." This action involves Wyeth and not its past or present, U.S. or foreign subsidiaries, past or present, U.S. or foreign divisions, or "any related companies." In addition, Wyeth objects to Impax's definition of "Wyeth" to the extent it includes former officers, directors, employees, agents, attorneys or representatives as potentially including entities outside of Wyeth's possession, custody, or control, or calls for information that may be subject to confidentiality agreements and/or attorney-client privilege. Consequently, in answering Impax's requests, Wyeth will construe "Wyeth" to mean only those portions of Wyeth involved with the research and development, manufacture, distribution, and/or sale of the venlafaxine hydrochloride extended release product EFFEXOR® XR in the United States. Wyeth further objects to Impax's instructions as unduly burdensome to the extent they seek to impose any further limitations or obligations upon Wyeth with respect to the production of documents within Wyeth's possession, custody, or control than those set forth above.

13. Wyeth objects to the production of "electronically produced, electronically stored, photostatic, photographed, recorded, or otherwise reproduced communications or records of every kind and description," documents as well as "computer files,

including backup OR archival copies" as overly broad, unreasonably cumulative and unduly burdensome. Subject to the General and Specific Objections, Wyeth will agree to produce TIFF images of documents produced by Wyeth in the *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.* litigation, Civil Action No. 03-CV-1293 (WJM) (hereinafter "Teva litigation") that were obtained from searches of Wyeth's relevant electronic systems, assuming that Impax is willing to provide its produced documents, electronic or otherwise, to Wyeth in TIFF format, and that Impax reimburses Wyeth for half of the cost of imaging copies of documents previously imaged for the Teva litigation and for the full cost of imaging copies of any documents produced solely in this litigation. Alternatively, Wyeth is willing to produce documents to Impax in hard paper copy format and Impax can reimburse Wyeth for the cost of those copies.

14. Wyeth objects to Impax's requests to the extent they call for information (including listing on a withheld document log) or documents generated subsequent to the February 10, 2003 cut-off date observed in the Teva litigation as irrelevant, overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The production or listing on a withheld document log of any document or information generated subsequent to this date should not be construed as a waiver of this objection with respect to any other document or information.

15. The incidental production of any document or information covered by any of Wyeth's General or Specific Objections shall not be construed as a waiver of the objection with respect to any other document or information.

16. Nothing in these responses should be construed as waiving rights or objections which otherwise might be available to Wyeth, nor should Wyeth's answering any discovery request be deemed an admission of relevancy, materiality or admissibility in evidence of the discovery requests or the responses thereto.

17. The General Objections apply to all of Impax's Document Request Nos. 1-4. To the extent that specific General Objections are cited herein in response to specific document requests, those specific citations are provided because they are believed to be particularly applicable to the request and are not to be construed as a waiver of any other General Objections applicable to documents falling within the scope of the request.

18. Although Wyeth objects generally to Impax's request that documents and things be produced at the offices of Heller Ehrman, LLP, Wyeth will forward to the offices of Heller Ehrman, LLP copies of produced documents with the understanding that Heller Ehrman, LLP will promptly reimburse Wyeth for the cost of those copies and that Impax will similarly forward its produced copies to the offices of Finnegan Henderson. Nevertheless, Wyeth retains the right to produce documents or things by making them available for inspection and copying by Impax at Wyeth's or Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.'s facilities.

19. Until a protective order is entered in this litigation, any production of Wyeth's confidential documents is on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

RESPONSE:

Subject to the General and Specific Objections above, Wyeth will produce documents marked as exhibits by Teva or Wyeth during Teva's depositions of Wyeth fact witnesses in the Teva litigation.

Date: July 26, 2006

Basil J. Lewris, Esq.
Linda A. Wadler, Esq.
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
Morris, Nichols, Arsht & Tunnell, LLP
Chase Manhattan Centre, 18th Floor
1201 North Market Street
Wilmington, DE 19899-1347
(302) 658-9200

Attorneys for Plaintiff Wyeth

EXHIBIT C

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

901 New York Avenue, NW ▪ Washington, DC 20001-4413 ▪ 202.408.4000 ▪ Fax 202.408.4400
www.finnegan.com

LINDA A. WADLER
202.408.4037
linda.wadler@finnegan.com

August 2, 2006

Via Facsimile

Samuel F. Ernst, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94140-2878

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Samuel:

I am writing in response to your letter of July 31, 2006 requesting production of certain documents by Friday, August 4th. Given the large number of documents involved (over 86,000 pages), your request for production in less than one week is not reasonable.

Specifically, Wyeth's objections and responses to the majority of Impax's document requests were due on the very day you wrote your letter - - July 31st. The Court's schedule, moreover, does not envision document production to be completed until October 10, 2006, notwithstanding the earlier date for amendment of pleadings. Impax itself has yet to produce a single document in response to Wyeth's document requests. Finally, the Court's Scheduling Order issued on July 13, 2006. If Impax felt that they needed particular documents on an expedited basis in connection with the amendment of pleadings deadline, it should have requested them earlier. Instead, Impax has waited almost three weeks to send a letter after the close of business on July 31st requesting production of tens of thousands of pages of documents in three business days. Your threat to file a motion to compel at this juncture is disturbing and entirely inappropriate.

We will accept your offer to pay for paper copies for production documents from Wyeth's NDA No. 20-699 and deposition transcripts of the named inventors, Dr. Mangano, and Mr. Alaburda and will begin processing those documents for production to you in the near future.[1] This acceptance is made without prejudice to our right to

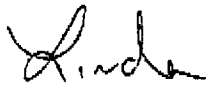
[1] In light of Impax counsel's August 1, 2006 letter to Teva Counsel, Henry Dinger, asking whether the deposition transcripts of the named inventors, Dr. Mangano and Mr. Alaburda contain Teva confidential information, we will wait to hear Teva's response before production of those deposition transcripts.

assert in the future that we will not later produce the same documents to you in TIFF format.

With respect to your request for the "Proposed Amended Complaint submitted…on or around April 1, 2005 as Exhibit D to a declaration of Lana Shvartsman," no such document exists. Exhibit D is a copy of a case. Although a proposed amended answer does exist, it was filed under seal subject to the protective order in that litigation by Teva. As a result, we cannot provide you with such information without getting approval from Teva. It is not reasonable to approach Teva in a piecemeal fashion with requests for de-designation of documents they have marked as subject to the protective order in the previous litigation. We need a more comprehensive way of addressing any production of documents subject to third party confidentiality.

Finally, it remains Wyeth's position that the Court entered the current Scheduling Order after considering the competing proposals of the parties. We see no need, therefore, for modification of Judge Farnan's schedule and believe that the Scheduling Order reflects the Court's views as to how the case should be managed.

Sincerely,



Linda A. Wadler

LAW/amn

cc: Mary B. Matterer, Esq. (via Facsimile)
Richard K. Herrmann, Esq. (via Facsimile)

EXHIBIT D

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

901 New York Avenue, NW ▪ Washington, DC 20001-4413 ▪ 202.408.4000 ▪ Fax 202.408.4400
www.finnegan.com

ROBERT A. POLLOCK
202.408.4081
robert.pollock@finnegan.com

August 4, 2006

VIA FACSIMILE
CONFIRMATION VIA
FEDERAL EXPRESS

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

Further to Impax's letter of July 31, 2006, requesting paper copies of Wyeth's NDA No. 20-699, and as part of Wyeth's document production, I am enclosing as part of a rolling production one box of documents containing the following range of production numbers:

WYETH 004-000001 - WYETH 004-001360.1;
WYETH 004-001361 - WYETH 004-002397; and
WYETH 004-002400 - WYETH 004 003005.

The enclosed documents are stamped CONFIDENTIAL or HIGHLY CONFIDENTIAL and SUBJECT TO PROTECTIVE ORDER. Until a formal protective order is in place, however, the enclosed documents should be maintained on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

With respect to your July 31, 2006 agreement to reimburse us for the reasonable cost of providing paper copies of NDA No. 20-699 and other selected documents, the cost for providing the enclosed documents is $180.18 (6¢ per page). Please reimburse us promptly for this amount.

Sincerely,

Robert A. Pollock

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

cc: Mary B. Matterer, Esq. (via Facsimile, without enclosures)
Richard K. Herrmann, Esq. (via Facsimile, without enclosures)

EXHIBIT E

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

901 New York Avenue, NW ▪ Washington, DC 20001-4413 ▪ 202.408.4000 ▪ Fax 202.408.4400
www.finnegan.com

ARIE M. MICHELSOHN, ESQ.
202.408.4160
arie.michelsohn@finnegan.com

September 12, 2006

VIA FACSIMILE

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 JJF (D. Del.)

Dear Daniel:

As part of Wyeth's continuing document production, 9 CDs containing documents in TIFF image format are available for your inspection. These documents bear the following range of production numbers:

WYETH 016-000001 - WYETH 016-002180;
WYETH 016-002182 - WYETH 016-002855;
WYETH 016-002862 - WYETH 016-003371;
WYETH 016-003373 - WYETH 016-003814;
WYETH 016-003833 - WYETH 016-004323;
WYETH 016-004325 - WYETH 016-005054;
WYETH 016-005056 - WYETH 016-007422;
WYETH 016-007430 - WYETH 016-008402;
WYETH 016-008404 - WYETH 016-008436;
WYETH 017-000001 - WYETH 017-002108;
WYETH 018-000001 - WYETH 018-016092;
WYETH 019-000001 - WYETH 019-022705;
WYETH 022-000001 - WYETH 022-003868;
WYETH 023-000001 - WYETH 023-001442;
WYETH 047-000001 - WYETH 047-008355;
WYETH 047-008389 - WYETH 047-010968;
WYETH 047-011681 - WYETH 047-014609;
WYETH 047-014611 - WYETH 047-015273;
WYETH 048-000001 - WYETH 048-004510;
WYETH 049-000001 - WYETH 049-004689;

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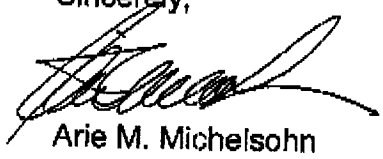
DUNNER LLP

WYETH 050-000001 - WYETH 050-011197;
WYETH 068-000001 - WYETH 068-000555;
WYETH 068-000557 - WYETH 068-009057;
WYETH 068-009062 - WYETH 068-010115;
WYETH 142-000001 - WYETH 142-000257;
WYETH 142-000273 - WYETH 142-003935;
WYETH 142-003950 - WYETH 142-004774;
WYETH 142-004819 - WYETH 142-004953;
WYETH 142-004956 - WYETH 142-007001;
WYETH 142-007006 - WYETH 142-007053;
WYETH 142-007102 - WYETH 142-007128;
WYETH 142-007137 - WYETH 142-007382;
WYETH 142-007449 - WYETH 142-007492;
WYETH 142-007498 - WYETH 142-008202; and
WYETH 213-000001 - WYETH 213-000023.

The enclosed documents are stamped CONFIDENTIAL or HIGHLY CONFIDENTIAL and SUBJECT TO PROTECTIVE ORDER. Until a formal protective order is in place, however, the documents should be inspected on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

Please contact us to arrange a mutually agreeable time for your inspection at our Reston, Virginia office. Alternatively, please let us know if you would prefer us to send you copies of these TIFF images at a cost of $6,501.18 (6¢ per page).

Sincerely,



Arie M. Michelsohn

AMM/jk

cc: Mary B. Matterer, Esq. (via Facsimile)
Richard K. Herrmann, Esq. (via Facsimile)

EXHIBIT F

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

901 New York Avenue, NW ▪ Washington, DC 20001-4413 ▪ 202.408.4000 ▪ Fax 202.408.4400
www.finnegan.com

ARIE M. MICHELSOHN, ESQ.
202.408.4180
arie.michelsohn@finnegan.com

September 18, 2006

VIA FACSIMILE

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 JJF (D. Del.)

Dear Daniel:

As part of Wyeth's continuing document production, 11 CDs containing documents in TIFF image format are available for your inspection. These documents bear the following range of production numbers:

WYETH 070-000001 - WYETH 070-000068;
WYETH 071-000001 - WYETH 071-000075;
WYETH 072-000001 - WYETH 072-000046;
WYETH 072-000056 - WYETH 072-000691;
WYETH 073-000001 - WYETH 073-000331;
WYETH 074-000001 - WYETH 074-000040;
WYETH 075-000001 - WYETH 075-000153;
WYETH 076-000001 - WYETH 076-000243;
WYETH 077-000001 - WYETH 077-000808;
WYETH 077-001003 - WYETH 077-014994;
WYETH 077-015133 - WYETH 077-015755;
WYETH 077-015896 - WYETH 077-016575;
WYETH 077-016607 - WYETH 077-017217;
WYETH 077-017335 - WYETH 077-021413;
WYETH 077-021417 - WYETH 077-025093;
WYETH 078-000001 - WYETH 078-000777;
WYETH 079-000001 - WYETH 079-000557;
WYETH 079-000559 - WYETH 079-001752;
WYETH 080-000001 - WYETH 080-003242;
WYETH 080-003346 - WYETH 080-014324;
WYETH 080-014326 - WYETH 080-014731;

WYETH 080-014733 - WYETH 080-015103;
WYETH 080-015105 - WYETH 080-015503;
WYETH 081-000001 - WYETH 081-002302;
WYETH 082-000001 - WYETH 082-000655;
WYETH 082-000667 - WYETH 082-000825;
WYETH 084-000001 - WYETH 084-000117;
WYETH 084-000123 - WYETH 084-000203;
WYETH 084-000206 - WYETH 084-000324;
WYETH 084-000327 - WYETH 084-000376;
WYETH 084-000378 - WYETH 084-000572;
WYETH 086-000001 - WYETH 086-005608;
WYETH 089-000003 - WYETH 089-000007;
WYETH 090-000001 - WYETH 090-002945;
WYETH 090-003249 - WYETH 090-007964;
WYETH 090-007973 - WYETH 090-009048;
WYETH 090-009053 - WYETH 090-010105;
WYETH 090-010142 - WYETH 090-010877;
WYETH 091-000001 - WYETH 091-001015;
WYETH 091-001098 - WYETH 091-001139;
WYETH 091-001175 - WYETH 091-001609;
WYETH 091-001611 - WYETH 091-002134;
WYETH 091-002184 - WYETH 091-005870;
WYETH 091-005878 - WYETH 091-006809;
WYETH 091-006829 - WYETH 091-007510;
WYETH 091-007523 - WYETH 091-008692;
WYETH 091-008700 - WYETH 091-009149;
WYETH 092-000001 - WYETH 092-000448;
WYETH 105-000001 - WYETH 105-000015;
WYETH 106-000001 - WYETH 106-000102;
WYETH 107-000001 - WYETH 107-011840;
WYETH 114-000001 - WYETH 114-001078;
WYETH 114-001085 - WYETH 114-002352;
WYETH 114-002355 - WYETH 114-002360;
WYETH 114-002364 - WYETH 114-002687;
WYETH 114-002690 - WYETH 114-003169;
WYETH 114-003172 - WYETH 114-004345;
WYETH 114-004347 - WYETH 114-006446;
WYETH 114-006448 - WYETH 114-006591;
WYETH 114-006593 - WYETH 114-006878;
WYETH 140-000001 - WYETH 140-000081;
WYETH 140-000083 - WYETH 140-000435;
WYETH 140-000437 - WYETH 140-000745;
WYETH 140-000747 - WYETH 140-000777;

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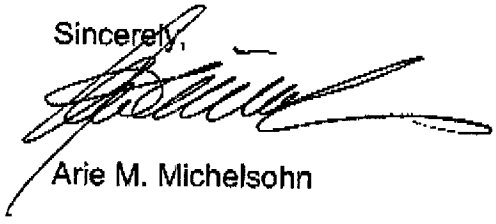
WYETH 140-000779 - WYETH 140-001147;
WYETH 140-001149 - WYETH 140-001466;
WYETH 140-001468 - WYETH 140-001508;
WYETH 140-001510 - WYETH 140-002564;
WYETH 141-000001 - WYETH 141-003934;
WYETH 141-003942 - WYETH 141-006070;
WYETH 141-006073 - WYETH 141-006075;
WYETH 141-006078 - WYETH 141-006079;
WYETH 141-006082 - WYETH 141-006083; and
WYETH 141-006086 - WYETH 141-006562.

The enclosed documents are stamped CONFIDENTIAL or HIGHLY CONFIDENTIAL and SUBJECT TO PROTECTIVE ORDER. Until a formal protective order is in place, however, the documents should be inspected on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

Please contact us to arrange a mutually agreeable time for your inspection at our Reston, Virginia office. Alternatively, please let us know if you would prefer us to send you copies of these TIFF images at a cost of $5,851.14 (6¢ per page).

Sincerely,



Arie M. Michelsohn

AMM/jk

cc: Mary B. Matterer, Esq. (via Facsimile)
Richard K. Herrmann, Esq. (via Facsimile)

EXHIBIT G

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

901 New York Avenue, NW ▪ Washington, DC 20001-4413 ▪ 202.408.4000 ▪ Fax 202.408.4400
www.finnegan.com

ARIE M. MICHELSOHN, ESQ.
202.408.4180
arie.michelsohn@finnegan.com

October 10, 2006

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

VIA FACSIMILE

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 JJF (D. Del.)

Dear Daniel:

As part of Wyeth's continuing document production, three boxes of paper copy materials are available for your inspection. These documents bear the following range of production numbers:

WYETH 004-000325 - WYETH 004-000361;
WYETH 004-019321 - WYETH 004-019542;
WYETH 010-000752 - WYETH 010-000756;
WYETH 010-001387 - WYETH 010-001410;
WYETH 010-001701 - WYETH 010-001705;
WYETH 010-001730;
WYETH 010-002180 - WYETH 010-002184;
WYETH 010-002917 - WYETH 010-002922;
WYETH 010-002937 - WYETH 010-002946;
WYETH 012-000034 - WYETH 012-000041;
WYETH 012-000061 - WYETH 012-000079;
WYETH 012-000693 - WYETH 012-000697;
WYETH 012-002190 - WYETH 012-002200;
WYETH 013-006127;
WYETH 018-000980 - WYETH 018-000992;
WYETH 020-005621 - WYETH 020-005630;
WYETH 020-005676 - WYETH 020-005689;
WYETH 020-005764 - WYETH 020-005771;
WYETH 020-005858 - WYETH 020-005868;
WYETH 020-006851;
WYETH 020-007573 - WYETH 020-007597;

WYETH 020-007599 - WYETH 020-007648;
WYETH 032-001212 - WYETH 032-001245;
WYETH 036-002483 - WYETH 036-002489;
WYETH 036-002491 - WYETH 036-002494;
WYETH 040-006980 - WYETH 040-006981;
WYETH 046-001571 - WYETH 046-001641;
WYETH 046-004835 - WYETH 046-004872;
WYETH 046-006058 - WYETH 046-006177;
WYETH 053-000331 - WYETH 053-000333;
WYETH 053-001323 - WYETH 053-001325;
WYETH 053-001462 - WYETH 053-001463;
WYETH 053-001500 - WYETH 053-001503;
WYETH 053-001602;
WYETH 053-001703 - WYETH 053-001707;
WYETH 053-001802 - WYETH 053-001827;
WYETH 055-000002 - WYETH 055-000038;
WYETH 065-005085 - WYETH 065-005089;
WYETH 090-005062;
WYETH 123-021970;
WYETH 123-021975 - WYETH 123-021978;
WYETH 123-021984 - WYETH 123-021992;
WYETH 123-021997 - WYETH 123-022006;
WYETH 126-010882 - WYETH 126-010984;
WYETH 126-011165 - WYETH 126-011167;
WYETH 126-013414 - WYETH 126-013509;
WYETH 133-003255 - WYETH 133-003271;
WYETH 180-014456 - WYETH 180-014462;
WYETH 203-009996 - WYETH 203-010000;
WYETH 203-023595 - WYETH 203-023604;
WYETH 203-028374 - WYETH 203-028380;
WYETH 203-031816 - WYETH 203-031926;
WYETH 203-032612 - WYETH 203-032802;
WYETH 203-036590 - WYETH 203-036735;
WYETH 203-037470 - WYETH 203-037492;
WYETH 203-037826 - WYETH 203-037833;
WYETH 203-037919 - WYETH 203-037971;
WYETH 204-000133 - WYETH 204-000166;
WYETH 205-004352 - WYETH 205-004355;
WYETH 300-003487 - WYETH 300-004768;
WYETH 301-000001 - WYETH 301-001595;
WYETH 318-007173 - WYETH 318-008724 and
WYETH 320-000001 - WYETH 320-000348.

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HENDERSON
FARABOW
GARRETT &
DUNNER LLP

The enclosed documents are stamped CONFIDENTIAL or HIGHLY CONFIDENTIAL and SUBJECT TO PROTECTIVE ORDER. Until a formal protective order is in place, however, the documents should be inspected on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

Please contact us to arrange a mutually agreeable time for your inspection at our Reston, Virginia office. Alternatively, please let us know if you would prefer us to send you copies of the TIFF images at a cost of $794.16 (12¢ per page).

Sincerely,

Arie Michelsohn

AAM/jtm

cc: Mary B. Matterer, Esq. (via Facsimile)
Richard K. Herrmann, Esq. (via Facsimile)

EXHIBIT H

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

901 New York Avenue, NW ▪ Washington, DC 20001-4413 ▪ 202.408.4000 ▪ Fax 202.408.4400
www.finnegan.com

ROBERT A. POLLOCK
202.408.4081
robert.pollock@finnegan.com

February 13, 2007

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

Via Facsimile (w/o enclosure) and FEDEX

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

Further to our letter dated February 9, 2007, we are writing to supplement our production of documents and things in accordance with Federal Rule of Civil Procedure 26(e). Accordingly, please find enclosed a DVD labeled WYPROD_105. This DVD contains the following documents, which were inadvertently omitted or defective on the originally produced 104 CDs:

WYETH003-000059 through 000076;
WYETH005-009036;
WYETH013-001071 through 001076;
WYETH013-001080 through 001083;
WYETH017-001654;
WYETH020-005764;
WYETH036-000001 through 002482;
WYETH036-002496 through 002524;
WYETH045-018171;
WYETH046-028381 through 030594;
WYETH046-083780 through 083798;
WYETH049-000095;
WYETH049-000220;
WYETH062-029908 through 029962;
WYETH080-007776 through 007794;
WYETH083-000001 through 000037;
WYETH083-000039 through 000483;
WYETH083-000509 through 000577;
WYETH083-000584 through 000979;

WYETH083-000996 through 001009;
WYETH083-001024 through 001089;
WYETH083-001103 through 001137;
WYETH083-001168 through 001366;
WYETH083-001369 through 001447;
WYETH093-006490 through 006506;
WYETH094-001230 through 001649;
WYETH101-005744;
WYETH104-000498 through 000913;
WYETH107-000001;
WYETH113-000659 through 000668;
WYETH123-062940 through 062941;
WYETH125-000858;
WYETH128-011111 through 011513;
WYETH128-017382 through 017446;
WYETH128-017486 through 017521;
WYETH143-000001 through 000012;
WYETH143-000016 through 000017;
WYETH143-000019 through 000089;
WYETH152-000261;
WYETH158-000001 through 000018;
WYETH158-000020 through 000021;
WYETH158-000023 through 000065;
WYETH158-000068 through 000254;
WYETH158-000256 through 000284;
WYETH158-000286 through 000342;
WYETH158-000349 through 000366;
WYETH158-000368 through 000369;
WYETH158-000371 through 000651;
WYETH158-000654 through 000722;
WYETH158-000725 through 000739;
WYETH158-000741 through 000792;
WYETH158-000794 through 000823;
WYETH158-000825 through 000904;
WYETH158-000906 through 000951;
WYETH158-000954 through 000984;
WYETH158-000987 through 001049;
WYETH158-001106 through 001494;
WYETH158-001554 through 001572;
WYETH161-000441 through 000455;
WYETH179-004584 through 004585;
WYETH179-004598 through 004599;
WYETH179-004628 through 004633;

WYETH179-004715;
WYETH180-025646;
WYETH180-025658;
WYETH202-000680 through 000684;
WYETH203-012244 through 012251;
WYETH203-026422 through 026434;
WYETH203-037988 through 037989;
WYETH203-038015; and
WYETH205-032508 through 032514.

The enclosed DVD further contains a supplemental production of TIFF images of documents bearing the following ranges of production numbers:

WYETH010-003648 through 003651;
WYETH010-003671 through 003674;
WYETH012-000034 through 000037;
WYETH013-014083 through 014182;
WYETH014-007241 through 007254;
WYETH020-005355 through 005364;
WYETH020-005764 through 005771;
WYETH020-006654 through 006677;
WYETH038-000001 through 000012;
WYETH038-000014 through 000080;
WYETH038-000082 through 000365;
WYETH047-008388;
WYETH052-001108 through 001118;
WYETH052-001128 through 001138;
WYETH072-000047 through 000055;
WYETH115-003879;
WYETH119-000422.1;
WYETH121-000247 through 000802;
WYETH121-000805 through 000817;
WYETH123-038535;
WYETH123-039843 through 039844;
WYETH123-068199 through 068395;
WYETH126-000001 through 001463;
WYETH126-001835 through 006380;
WYETH126-006470 through 006989;
WYETH126-007041 through 008474;
WYETH126-008497 through 009153;
WYETH126-009156 through 009456;
WYETH126-009513 through 009847;
WYETH126-009858 through 010045;

WYETH126-010185 through 010200;
WYETH126-010234 through 010392;
WYETH126-010407 through 010487;
WYETH126-010555 through 011427;
WYETH126-011506 through 011568;
WYETH126-011638 through 013306;
WYETH126-013384 through 013509;
WYETH142-003935;
WYETH180-006137;
WYETH203-025306 through 025315;
WYETH203-034541 through 034548;
WYETH203-036498 through 036569; and
WYETH210-000001 through 000003.

The DVD also contains the document bearing the production number WYETH202-000673.1, which was inadvertently produced in unredacted form, rather than as redacted for Mr. Clark's deposition as Clark Exhibit No. 72. The redactions pertain to sensitive product information having nothing to do with venlafaxine or any issue in this case. Please destroy all electronic and paper copies of the original unredacted document produced to you (other than the original CD containing the document).

The enclosed documents and things are stamped CONFIDENTIAL or HIGHLY CONFIDENTIAL and SUBJECT TO PROTECTIVE ORDER.

Please also note that our February 9, 2007 production to you included one CD bearing production number WYETH212-003065, which contains data in SAS format that was not identified in the cover letter.

Finally, as also indicated in our February 9 letter, in lieu of replacing the original 104 CDs that were produced to you, we are currently preparing a hard drive containing Wyeth's entire electronic document production. This hard drive will include the documents that we are producing in DVD WYPROD_105. When you receive this hard drive, please return the original 104 CDs and DVD WYPROD_105 to us.

Sincerely,

Robert A. Pollock

cc: Mary B. Matterer, Esq. (via Facsimile, without enclosure)

EXHIBIT I

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	)	Civil Action No.: 06-222 JJF

DEFENDANT IMPAX LABORATORIES, INC.'S

FIRST SET OF INTERROGATORIES (NOS. 1-19)

Pursuant to Federal Rule of Civil Procedure 33, Defendant Impax Laboratories, Inc. requests that Plaintiff Wyeth answer the following interrogatories within 30 days of the date of service hereof.

DEFINITIONS

When used in the following interrogatories, the following definitions apply:

1. "WYETH" or "PLAINTIFF" means Plaintiff Wyeth and that company as it was previously named and any related companies, parents, divisions, or subsidiaries, past or present, located in the U.S. or abroad, and the past or present directors, officers, employees, agents, representatives or attorneys thereof.

2. "IMPAX" or "DEFENDANT" means Defendant IMPAX Laboratories, Inc. and its past or present directors, officers, employees, agents, representatives or attorneys known to WYETH.

3. "CONCERNING" means referring to, relating to, regarding, reflecting, associated with, comprising, constituting, containing, demonstrating, describing,

H. If any interrogatory is unclear or ambiguous to you, you are requested to contact undersigned counsel as soon as possible so that the interrogatory can be clarified to avoid unnecessary delays in discovery.

INTERROGATORIES

INTERROGATORY NO. 1:

IDENTIFY all PERSONs who have knowledge of any of the facts or events referred to in the Complaint filed by WYETH in the above-captioned action, or any amendments thereto, including without limitation paragraphs 14-19, 25-30, 36-41 of the Complaint, and state what knowledge each PERSON has.

INTERROGATORY NO. 2:

IDENTIFY all PERSONs who contributed to the conception and reduction to practice or attempted reduction to practice of the inventions claimed in the PATENTS IN SUIT and state the nature of each such PERSON's contribution.

INTERROGATORY NO. 3:

IDENTIFY all PERSONs who were involved in the research and development of EFFEXOR XR including, but not limited to, analytical testing and development, formulation studies and development, synthesis routes, stability testing, submissions to the FDA in connection with any INDA CONCERNING EFFEXOR XR or NDA 20-699, or performing clinical studies 600B-208-US, 600B-209-US, or 600B-367-EU, or any revisions thereto, and state the nature of each such PERSON's involvement.

INTERROGATORY NO. 4:

IDENTIFY all PERSONs who participated in the prosecution of the PATENTS IN SUIT or any other patents or patent applications which claim priority from or through, or from which priority is claimed by, the PATENTS IN SUIT.

INTERROGATORY NO. 10:

For each asserted claim of the PATENTS IN SUIT, identify all written description support, either explicit or inherent, in the specification of the PATENTS IN SUIT.

INTERROGATORY NO. 11:

For each invention allegedly disclosed and claimed in the PATENTS IN SUIT:

(a) IDENTIFY every opinion of counsel prepared or considered by you or on your behalf, whether oral or in writing, which relates to: patentability, novelty, validity, invalidity, state of the art, enforceability, scope, or infringement;

(b) IDENTIFY any search of prior art conducted by WYETH or on WYETH's behalf;

INTERROGATORY NO. 12:

For each invention allegedly disclosed and claimed in the PATENTS IN SUIT:

(a) state the DATE of its first conception;

(b) state the DATE of its reduction to practice;

(c) state the first DATE it was offered for sale to any person or company anywhere in the world;

(d) state the DATE it was first sold or offered for sale in the United States.

INTERROGATORY NO. 13:

State whether WYETH has granted any licenses under the PATENTS IN SUIT, and for each such license:

(a) IDENTIFY the licensee;

Dated: June 30, 2006

MARY B. MATTERER (I.D. No. 2696)
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Ave., 10th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800

M. PATRICIA THAYER (*pro hac vice*)
JOHN M. BENASSI (*pro hac vice*)
JESSICA R. WOLFF (*pro hac vice*)
SAMUEL F. ERNST (*pro hac vice*)
HELLER EHRMAN LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92101
Telephone: (858) 450-8400
Facsimile: (858) 450-8499
Attorneys for Defendant
IMPAX LABORATORIES, INC.

EXHIBIT J

ENTIRE EXHIBIT REDACTED

EXHIBIT K

ENTIRE EXHIBIT REDACTED

EXHIBIT L

ENTIRE EXHIBIT REDACTED

EXHIBIT M

ENTIRE EXHIBIT REDACTED

EXHIBIT N

ENTIRE EXHIBIT REDACTED

EXHIBIT O

ENTIRE EXHIBIT REDACTED

EXHIBIT P

ENTIRE EXHIBIT REDACTED

EXHIBIT Q

HellerEhrman LLP

November 20, 2006

Via E-mail and U.S. Mail

Daniel N. Kassabian
Daniel.Kassabian@hellerehrman.com
Direct +1.415.772.6098
Direct Fax +1.415.772.1796
Main +1.415.772.6000
Fax +1.415.772.6268

40443.0005

Linda A. Wadler, Esq.
Finnegan Henderson Farabow
Garrett & Dunner LLP
901 New York Ave., N.W.
Washington, D.C. 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.
U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF

Dear Linda:

Please find enclosed a copy of Defendant Impax Laboratories, Inc.'s Notice Of Deposition Of Wyeth Pursuant To Fed. R. Civ. P. 30(b)(6). Please let us know of a good time to meet and confer over the logistics of scheduling of this deposition, including which topics will be covered on which days and where the deposition will take place. As we wish to begin this deposition in December, we look forward to your prompt reply.

Best regards,

D. Kassabian

Daniel N. Kassabian

Enclosure

cc: M. Patricia Thayer, Esq.
Jessica R. Wolff, Esq.
Samuel F. Ernst, Esq.
Mary B. Matterer, Esq.
Jack B. Blumenfeld, Esq.
Karen Jacobs Louden, Esq.

SF 1320892 v1
(40443.0005)

EXHIBIT R

HellerEhrman LLP

January 22, 2007

Via E-mail and U.S. Mail

Daniel N. Kassabian
Daniel.Kassabian@hellerehrman.com
Direct +1.415.772.6098
Direct Fax +1.415.772.1796
Main +1.415.772.6000
Fax +1.415.772.6268

40443.0005

Linda A. Wadler, Esq.
Barbara R. Rudolph, Esq.
Finnegan Henderson Farabow
Garrett & Dunner LLP
901 New York Ave., N.W.
Washington, D.C. 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.
U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF

Dear counsel:

Please find enclosed Impax's Amended Notice Of Deposition Of Wyeth Pursuant To Fed. R. Civ. P. 30(b)(6). We believe it notices topics that are either directly relevant to, or reasonably calculated to lead to relevant evidence for, the issues in this litigation. At the same time, the number of topics is not unduly burdensome given the scope of this litigation, and the topics are sufficiently particular to allow Wyeth to prepare one or more witnesses to answer questions with respect to the same.

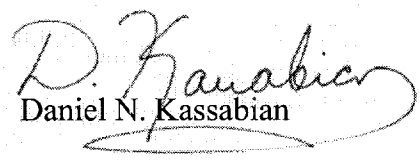
We wish to move forward with topic nos. 2, 21-24 and 28 expeditiously, and have noticed the deposition for February 5, 2007, for this reason. We understand that it is Wyeth's position that these topics capture privileged subject matter, but at the same time it would be unreasonable for Wyeth to take the position that each and every question related to the same will result in the invocation of privilege. Indeed, to the extent the parties disagree on the contours of the privilege being asserted, having the deposition prior to the conference with the Court on February 7th will allow us to better define the areas of disagreement so as to raise them with the Court. We believe the Court will prefer such an approach as compared to discussing areas of privilege in the abstract, or engaging in written discovery and endless meet and confer as to privilege objections for to the same. Moreover, if Wyeth is willing to designate the patent prosecutor with the most knowledge regarding the prosecution of the patents-in-suit for topic nos. 2, 21-24 and 28, Impax is willing to conduct the personal deposition of this person at the same time. This is being suggested in an effort to reduce duplication, understanding of course that if Wyeth instead chooses to prepare as its designee someone without any personal knowledge as to the relevant prosecution facts, this will result

in a separate, personal deposition of the patent prosecutor with the most knowledge, and possibly a further deposition on these topics in instances where the first corporate designee lacked the knowledge necessary to answer the questions posed.

If Wyeth refuses to produce any witness on February 5th or any other time prior to the Court's conference on February 7th, please let us know the reasons for its refusal immediately. To the extent all issues cannot be resolved prior to the conference, we intend to raise the outstanding ones with the Court at that time.

We look forward to your prompt reply.

Best regards,



Daniel N. Kassabian

Enclosure

cc: M. Patricia Thayer, Esq.
Jessica R. Wolff, Esq.
Samuel F. Ernst, Esq.
Mary B. Matterer, Esq.
Jack B. Blumenfeld, Esq.
Karen Jacobs Louden, Esq.

SF 1340459 v1
(40443.0005)

EXHIBIT S

HellerEhrman LLP

August 4, 2006

Via Federal Express

Daniel N. Kassabian
Daniel.Kassabian@hellerehrman.com
Direct +1.415.772.6098
Direct Fax +1.415.772.1796
Main +1.415.772.6000
Fax +1.415.772.6268

40443.0005

Linda A. Wadler, Esq.
Finnegan Henderson Farabow
Garrett & Dunner LLP
901 New York Avenue, NW
Washington, D.C. 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.
U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF

Dear Linda:

Please find enclosed a CD containing TIFF images and a Concordance load file of Impax's ANDA 78-057, Bates labeled IMPAX0000001 - IMPAX0004513. Please note that these documents have been marked "Confidential – Outside Counsel Eyes Only" pursuant to Local Rule 26.2, and should be treated accordingly until the parties can agree to a protective order in this action.

Best regards,

Daniel N. Kassabian

Enclosure

EXHIBIT T

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	C. A. No. 06-222 (JJF)

PLAINTIFF'S RESPONSES AND OBJECTIONS TO IMPAX'S SECOND REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 5-86)

Plaintiff, Wyeth, hereby responds to the First Request for Production of Documents and Things (Nos. 5-86) served by Defendant Impax Laboratories, Inc. (hereinafter "Impax") on June 30, 2006 via hand delivery.

GENERAL OBJECTIONS

1. Wyeth objects to any request to the extent it seeks to impose on Wyeth any obligation not required by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the District of Delaware.

2. Wyeth objects generally to the production of documents and things protected by the attorney-client privilege, work product immunity, or any other applicable privilege. To the extent that such documents and things not otherwise objectionable are called for by Impax's requests, they will be identified in a listing of withheld documents which will be prepared in due course and exchanged with Impax on a mutually agreed upon date.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents concerning "intellectual property rights or technology transfer" other than the patents in suit as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive product information.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 48:

All DOCUMENTS and THINGS CONCERNING NDA 20-699, including without limitation submissions to the FDA, the listing of the PATENTS IN SUIT in the ORANGE BOOK, clinical trials, efficacy studies, and supplemental and related NDAs.

OBJECTION:

Wyeth objects to this request to the extent it seeks any documents whatsoever "CONCERNING NDA 20-699" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. For example, Wyeth objects to this request as overly broad, unduly burdensome and irrelevant to any issue in this litigation to the extent it seeks documents concerning the manufacture of venlafaxine

hydrochloride itself, specifications and analytical methods for venlafaxine hydrochloride itself, batch records, stability, toxicology, packaging, quality control, plant layouts, raw patient data from which patient identifying information must be redacted, etc. Wyeth also objects to this request to the extent it seeks "related NDAs" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log. Those documents include, *inter alia*, a complete copy of the Table of Contents for New Drug Application (NDA) No. 20-699 as well as portions of the following sections of NDA No. 20-699: Chemistry Manufacturing and Controls, Labeling, Human Pharmacokinetics and Bioavailability, Clinical, Safety Update, Patent and Exclusivity Information and Patent Certification Information.

IMPAX DOCUMENT REQUEST NO. 49:

All DOCUMENTS and THINGS CONCERNING modifications made to the NDA 20-699, beginning with the initial experimentation through the current approval by the FDA, including without limitation laboratory notebooks, experimental or exploratory records, analytical profiles, analytical testing methods, specifications, certificates of analysis, correspondence, data, agreements, invention disclosures, and applications filed with any patent office that are now or have been at any time assigned to WYETH.

OBJECTION:

Wyeth objects to this request to the extent it seeks any documents whatsoever "CONCERNING modifications made to the NDA 20-699" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. For example, Wyeth objects to this request as overly broad, unduly burdensome and irrelevant to any issue in this litigation to the extent it seeks documents concerning the manufacture of venlafaxine hydrochloride itself, specifications and analytical methods for venlafaxine hydrochloride itself, batch records, stability, toxicology, packaging, quality control, plant layouts, raw patient data from which patient identifying information must be redacted, etc. Wyeth further objects to this request to the extent it seeks "applications filed with any patent office that are now or have been at anytime assigned to Wyeth" as unduly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, boundless and meaningless in the context of this request, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks publicly available files relating to patents and patent applications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. Wyeth further objects to this request to

the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "invention disclosures."

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log. Those documents include, *inter alia*, a complete copy of the Table of Contents for New Drug Application (NDA) No. 20-699 as well as portions of the following sections of NDA No. 20-699: Chemistry Manufacturing and Controls, Labeling, Human Pharmacokinetics and Bioavailability, Clinical, Safety Update, Patent and Exclusivity Information and Patent Certification Information.

IMPAX DOCUMENT REQUEST NO. 50:

All DOCUMENTS and THINGS CONCERNING clinical studies 600B-208-US, 600B-209-US, 600B-367-EU, including without limitation clinical results, patient reports, corrected or amended reports, statistical analysis, records of incidence of nausea or emesis, laboratory notebooks, experimental or exploratory records, analytical profiles, analytical testing methods, specifications, certificates of analysis, correspondence, data, agreements, invention disclosures, and applications filed with any patent office that are now or have been at any time assigned to WYETH.

OBJECTION:

Wyeth objects to this request to the extent it seeks any documents whatsoever "CONCERNING clinical studies 600B-208-US, 600B-209-US, 600B-367-EU" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence

to the extent it seeks the production of voluminous raw data and data compilations as well as raw patient data from which patient identifying information must be redacted, etc. Wyeth further objects to this request to the extent it seeks "applications filed with any patent office that are now or have been at anytime assigned to Wyeth" as unduly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, boundless and meaningless in the context of this request, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks publicly available files relating to patents and patent applications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "invention disclosures."

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 51:

All DOCUMENTS and THINGS CONCERNING any INDA for an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE, including without limitation submissions to the FDA, or any modifications thereto.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents "CONCERNING any INDA for an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE"

as overly broad, unduly burdensome, irrelevant to any issue in the suit and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents concerning INDAs other than INDA No. 41,412 as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 52:

All DOCUMENTS and THINGS CONCERNING public meetings anywhere in the world at which the NAMED INVENTORS, or any other PERSON presented orally or in writing information or research results or otherwise discussed an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE, including without limitation all presentation materials, whether in written or electronic form, abstracts, notices and all other DOCUMENTS CONCERNING these presentations.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning "public meetings anywhere in the world" regarding "an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE" as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible

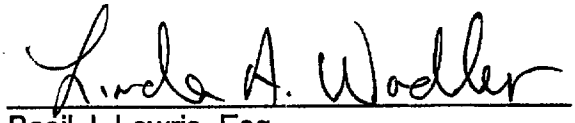
equally on the requesting party. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own. Wyeth further objects to this request to the extent it seeks documents and things not within Wyeth's possession, custody, or control and/or subject to the rights of third parties not affiliated with Wyeth.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

Dated: July 31, 2006

By:



Basil J. Lewris, Esq.
Linda A. Wadler, Esq.
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
Chase Manhattan Centre, 18th Floor
1201 North Market Street
Wilmington, DE 19899-1347
(302) 658-9200

Attorneys for Plaintiff Wyeth

EXHIBIT U

PR Newswire - Press Release

Wyeth Receives Approvable Letter From FDA for Pristiq (Desvenlafaxine Succinate) for the Treatment of Major Depressive Disorder

01.23.07, 3:39 PM ET

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MADISON, N.J., Jan. 23 /PRNewswire-FirstCall/ -- Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), announced today that the Company has received an approvable letter from the U.S. Food and Drug Administration (FDA) for Pristiq(TM) (desvenlafaxine succinate), a serotonin-norepinephrine reuptake inhibitor (SNRI) studied as a treatment for adult patients with major depressive disorder (MDD). The letter was received January 22.

"The approvable letter is in line with Wyeth's expectations and we remain on track with our plans for Pristiq," says Joseph Mahady, President, Wyeth Pharmaceuticals -- North America and Global Businesses. "We are working toward resolution of all outstanding issues at our manufacturing site in Guayama, Puerto Rico and have already made significant progress in meeting previously established commitments."

According to the approvable letter, FDA approval of Pristiq is subject to several conditions, including the following:

* A satisfactory FDA inspection of the Company's Guayama, Puerto Rico facility, which is where Pristiq will be

manufactured * Several post-marketing commitments, including submission of long-term relapse prevention, low dose and pediatric studies * Additional clarity around the Company's product education plan for physicians and patients * Confirmation by the FDA of the acceptability of the proprietary name, Pristiq As the Company has already communicated, launch timing for the MDD indication is predicated on three elements -- final FDA approval for Pristiq as a treatment for adult patients with MDD, the results of ongoing MDD studies at lower dosage levels, and the progress of FDA review of Wyeth's separate New Drug Application (NDA) for vasomotor symptoms (VMS) associated with menopause. Importantly, while the approvable letter requires some post-marketing commitments, the FDA does not require that any additional clinical studies be submitted prior to the approval of Pristiq.

"Given the importance of Pristiq, we are committed to ensuring the most complete profile and product information is available to physicians and patients at the time of this product's launch," Mahady says.

About Pristiq

Pristiq is an SNRI studied as a potential treatment for adult men and women with MDD. Wyeth submitted a NDA for MDD on December 22, 2005. The Company has also filed a NDA for VMS associated with menopause and expects an FDA action letter in the second quarter of 2007. If approved, Pristiq will be the first and only non-hormonal medicine for the treatment of VMS associated with menopause. Wyeth is a leader in both neuroscience and women's health care.

Wyeth discovered and developed the first SNRI approved by the FDA, which is currently the most widely used antidepressant in the world. Pristiq represents Wyeth's latest efforts and continued commitment to developing therapies to help improve the lives of patients suffering from mental health disorders.

According to a large depression trial funded by the National Institute of Mental Health, only 28 percent of patients with depression achieved remission with initial antidepressant treatment. This leaves a large percentage of patients still suffering from depression. Clearly, additional medicines are needed for treating MDD.

About Antidepressants

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder and other psychiatric disorders. Anyone considering the use of any antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are on such therapy should be observed closely for clinical worsening, suicidality or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with their prescriber.

About Major Depressive Disorder

Major depressive disorder is a serious medical condition that is different from "feeling blue" and is not something that people just "get over." Criteria for major depressive disorder include five or more of the following symptoms that have been present for at least two weeks, and at least one of the symptoms must be either depressed mood or loss of interest or pleasure.

* Depressed mood * Loss of interest or pleasure * Changes in appetite

or weight * Changes in sleeping patterns * Psychomotor agitation or retardation * Fatigue or low energy * Feeling worthless or guilty for no reason * Difficulty thinking or concentrating * Thoughts of death or suicide Further, people with major depressive disorder may experience clinically significant distress or impairment in social, occupational or other important areas of functioning. If a person experiences these symptoms, he or she should speak with a health care professional.

Major depressive disorder is a common mental disorder, affecting about 121 million people worldwide. In the United States, it is estimated that depression affects about 19 million American adults each year. The lifetime risk of major depression has been assessed from 10 to 25 percent for women and five to 12 percent for men. Research has shown that hormonal changes, including estrogen decline, or life stressors experienced by women may contribute to a major depressive episode.

About Wyeth Pharmaceuticals

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology and vaccines. Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of pharmaceuticals, vaccines, biotechnology products and nonprescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include risks associated with the inherent uncertainty of the timing and success of product research, development and commercialization (including with respect to our pipeline products), drug pricing and payment for our products by government and third party-payors, manufacturing, data generated on the safety and efficacy of our products, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade buying patterns, global business operations, product liability and other types of litigation, the impact of legislation and regulatory compliance, intellectual property rights, strategic relationships with third parties, environmental liabilities, and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A, Risk Factors." We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

For more information, visit www.wyeth.com .

SOURCE Wyeth Pharmaceuticals -0- 01/23/2007 /CONTACT: Gwen Fisher of Wyeth Pharmaceuticals, +1-484-865-5160, Mobile, +1-215-407-1548; or Doug Petkus, +1-973-660-5218, or Investor Contact, Justin Victoria, +1-973-660-5340, both of Wyeth/ /Web site: http://www.wyeth.com / (WYE) CO: Wyeth Pharmaceuticals ST: New Jersey IN: MTC HEA SU: FDA BR-AA -- NYTU149 -- 2830 01/23/2007 15:37 EST http://www.prnewswire.com

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EXHIBIT V

Class	Subclass
424	461

ISSUE CLASSIFICATION

PATENT NUMBER
6274171
6274171

U.S. UTILITY Patent Application

O.I.P.E.
PATENT DATE
AUG 14 2001

APPLICATION NO.	CONT/PRIOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
09/488629	D	424	461	1615	SPEAR

APPLICANTS
Deborah Sherman
John Clark
John Lamer
08/964,328

TITLE
Extended release formulation

PTO-2040
12/99

ISSUING CLASSIFICATION

ORIGINAL CLASS	ORIGINAL SUBCLASS	CROSS REFERENCE(S) CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					
424	461	424	457	458	459			
INTERNATIONAL CLASSIFICATION		514	781	962				
A61K 9/52								
A61K 9/54								
A61K 9/62								

☐ Continued on Issue Slip inside File Jacket

☐ TERMINAL DISCLAIMER

☐ The term of this patent subsequent to _____ (date) has been disclaimed.

☐ The term of this patent shall not extend beyond the expiration date of U.S Patent. No. _____

☐ The terminal ____ months of this patent have been disclaimed.

DRAWINGS Sheets Drwg.	Figs. Drwg.	Print Fig.	CLAIMS ALLOWED Total Claims	Print.Claim for O.G.
0	0	0	25	1

_____ (Assistant Examiner) _____ (Date)

JAMES M. SPEAR
PRIMARY EXAMINER
ART UNIT 1615
James M. Spear 5-7-01
(Primary Examiner) (Date)

(Legal Instruments Examiner) (Date)

NOTICE OF ALLOWANCE MAILED
5/09/01

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Date Paid: 6/13/01

ISSUE BATCH NUMBER
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The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, Sections 122, 181 and 368. Possession outside the U.S. Patent & Trademark Office is restricted to authorized employees and contractors only.

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Issue Fee In File

(FACE)

PATENT APPLICATION

09488629

Jc542 U.S. PTO
09/488629
01/20/00

FEB 16 0035

INITIALS

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/488,629	01/20/00	SHERMAN D	AHP-95011-P2

HM12/0104

Egon E Berg
American Home Products Corporation
Patent Law Department 2B
One Campus Drive
Parsippany NJ 07054

EXAMINER	
SPEAR, J	
ART UNIT	PAPER NUMBER
1615	4

DATE MAILED: 01/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary	Application No. 09/488,629	Applicant(s) SHERMAN, ET AL.
	Examiner JAMES M. SPEAR	Group Art Unit 1615

☒ Responsive to communication(s) filed on *Jan 20, 2000*

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *THREE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-22* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *21 and 22* is/are allowed.

☒ Claim(s) *1, 12, 18, and 19* is/are rejected.

☒ Claim(s) *2-11, 13-17, and 20* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2,5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 18 and 19 contain the trademark/trade name HYDROXYPROPYLMETHYLCELLULOSE TYPE 2208 and TYPE 2910 and ETHYLCELLULOSE TYPE HG 2834. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to

identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a hydroxyalkylcellulose (hydroxypropylmethylcellulose) and ethylcellulose and, accordingly, the identification/description is indefinite. It is unclear as to what the type terminology is indicative of and how the various compounds differ based on the number notation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAinsh et al U.S. 4,138,475 in view of Wong et al U.S. 5,552,429.

McAinsh et al shows a hard gelatin capsule comprised of spheroids coated with a mixture of ethylcellulose and hydroxypropylmethylcellulose. The active agent propranolol is blended with microcrystalline cellulose to formulate the core spheroid. See Abstract, example and claim 1. The reference does not show venlafaxine. Wong et al is relied on for teaching extended release dosage forms comprised of the same ingredients as McAinsh et al including the drugs venlafaxine and propranolol. See column 4, lines 7-10, column 6, lines 54-55, column 7, lines 18-22, formulation 5. To use the venlafaxine of Wong et al in the McAinsh et al capsule with a reasonable expectation of success would have been obvious to one of ordinary skill in the art.

Given the teachings of the prior art it would be reasonable to expect that propranolol common to both McAinsh et al and Wong et al could be combined with venlafaxine in a sustained release dosage form to increase patient compliance when the need arises to administer both drugs. The motivation being a desire to obtain optimum drug efficacy over a prolonged period of time while reducing the total number of dosages required.

Claims 2-11, 13-17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 1, 12, 18 and 19 are rejected.

Claims 21 and 22 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Spear whose telephone number is (703) 308-2457. The examiner can normally be reached on Monday thru Friday from 6:30 A.M. to 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-3592 or 308-4556.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**thurman.page@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

James M. Spear

January 3, 2001

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
ART UNIT 1615

ATTACHMENT TO AND MODIFICATION OF NOTICE OF ALLOWABILITY (PTO-37)

(November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored[1]:

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to comply will result in ABANDONMENT of this application. ~~Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).~~

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

---

[1] The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See *"Changes to Implement the Patent Business Goals"*, 65 *Fed. Reg.* 54603, 54629, 54641, 54670, 54674 (September 8, 2000), 1238 *Off. Gaz. Pat. Office* 77, 99, 110, 135, 139 (September 19, 2000).

Notice of References Cited

Application No.	Applicant(s)
09/488,629	SHERMAN, ET AL.

Examiner	Group Art Unit	Page 1 of 1
JAMES M. SPEAR	1615	

U.S. PATENT DOCUMENTS

		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
	A	4,138,475	2/1979	McAinsh, et al	424	19
	B	5,552,429	9/1996	WONG, ET AL.	514	415
	C					
	D					
	E					
	F					
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	L					
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
	N						
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

		DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
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Name of Person Mailing Paper or Fee

Judith A. Johnston
Signature of Person Mailing Paper or Fee

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AHP-95011-P2
PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Deborah M. Sherman
John C. Clark
John U. Lamer

Serial No.: 09/488,629 **Confirmation No.:** 4728

Filed: January 20, 2000 **Examiner:** J. Spear

For: Extended Release Formulation **Group:** 1615

6/a Suggs 3-5-01

Assistant Commissioner for Patents
Washington, D.C. 20231

REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. §1.111

Sir:

This is in response to the Office Action issued in connection with this case. The Office Action has been carefully reviewed and the following response prepared. Please amend the application as follows:

In the Claims:

Please cancel Claim 1.

2 Please amend the claims as follows: 2

1 2. An extended release formulation [according to Claim 1] of venlafaxine hydrochloride comprising a pharmaceutically acceptable capsule [wherein the] containing spheroids [are] comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 94% microcrystalline cellulose, NF, by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropyl-methylcellulose, USP, wherein the spheroids are coated with a film coating composition comprised of ethyl cellulose and hydroxypropylmethylcellulose.

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02 FC:103 54.00 CH

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A

12. (Amended) An extended release formulation according to Claim 2 wherein the spheroids are composed of about 37% by weight of venlafaxine hydrochloride, about 0.5% by weight of hydroxypropylmethylcellulose [2208], and about 62% by weight of microcrystalline cellulose.

17. (Amended) [A film coating composition] An extended release formulation according to Claim 2 wherein the film coating composition is [which is] comprised of about 85% by total weight of film coating of ethyl cellulose having 44.0 - 51.0% content of ethoxy groups, and about 15% by total weight of film coating of hydroxypropylmethylcellulose having a methoxy content of 28.0-30.0% and a hydroxypropoxy group content of 7.0-12.0%.

18. (Amended) [A film coating composition] An extended release formulation according to Claim 2 [which] wherein the film coating composition is comprised of 85% by weight of ethyl cellulose having an ethoxy content of 44.0-51% and a viscosity of 50 cps for a 5% aqueous solution, [type HG 2834] and 15% by weight of hydroxypropylmethylcellulose having a viscosity of 6 cps at 2% aqueous solution with a methoxy content of 28-30% and a hydroxypropoxy content of 7-12% [type 2910].

19. (Amended) An extended release formulation of venlafaxine hydrochloride for once daily administration which comprises spheroids containing 37.3% venlafaxine, 62.17% microcrystalline cellulose and 0.5% hydroxypropylmethylcellulose [type 2208], coated with a quantity of a mixture comprised of 85% ethyl cellulose [type HG 2834] and 15% hydroxypropylmethylcellulose [type 2910] sufficient to give coated spheroids having a dissolution profile [which gives the desired release rate over a 24 hour period] in USP Apparatus 1 (basket) at 100 rpm in purified water at 37°C:

Time	Average % Venlafaxine HCl Released
2	<30
4	30-55
8	55-80
12	65-90
24	>80.

In Claims 3, 4, 6 and 11, please delete "Claim 1" and insert --Claim 2-- therefor.
In Claim 8, please delete "Claim 6" and insert --Claim 2-- therefor.
In Claims 13, 14, 15, and 16, please delete "A composition" and insert --An extended release formulation-- therefor.

Please add the following new claims:

~~23.~~ A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

~~24.~~ A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

~~25.~~ A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

~~26.~~ A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses o venlafaxine hydrochloride which comprises administering orally to a patient in need

thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

Remarks

Claims 1-22 were pending in this case. Applicants appreciate the Examiner's indication that Claims 21 and 22 are allowed and that Claims 2-11, 13-17 and 20 are allowable. Claims 1, 12, 18 and 19 were rejected. Claim 1 was cancelled by this paper, without prejudice to its presentation in a divisional application. Claim 2 was rewritten in independent form by incorporating the subject matter of Claim 1. Claims 3, 4, 6 and 11 were amended to depend from Claim 2 rather than from cancelled Claim 1. Claims 12, 18 and 19 were amended to delete reference to trademarks/-tradenames. Claim 19 was also amended to specifically enumerate the dissolution profile referenced in the claim. Claims 13-18 were amended to proper dependen form by conforming their preambles to that of Claim 2 from which Claims 13-18 depend. Claims 8-10 were amended to depend from Claim 2 rather than from Claim 6 (which depends from Claim 2). New Claims 23 through 26 were added. New Claims 23 through 26 are supported throughout the specification and particularly, for example, at page 3, lines 14-19. No change in claim scope is intended by these amendments.

Claims 12, 18 and 19 were rejected under 35 U.S.C. §112, second paragraph, because they recited trademarks or tradenames. Applicants have amended Claims 12, 18 and 19 to delete trademarks/names. Reference is made generically instead to hydroxypropylmethylcellulose or ethylcellulose as supported, for example, in Claim 2, and in the specification at Page 6, line 30 through Page 7, line 4. Claims 12, 18 and 19 should not be limited to the particular hydroxypropylmethylcellose or ethylcellulose identified by the trademark/name.

Claim 1 was rejected under 35 U.S.C. §103(a). Claim 1 was cancelled, without prejudice to its presentation in a divisional application. Accordingly, this rejection is moot.

Claims 2-11, 13-17 and 20 were objected to as being dependent upon a rejected base claim. Claim 2 has been rewritten as an independent claim. Claims 3-

11, 13-17 and 20 have been amended so that they depend, directly or indirectly, from allowable Claim 2. Accordingly, this objection should be withdrawn.

In view of the foregoing, Claims 2-26 are in condition ready for allowance. An early and favorable Notice of Allowance is respectfully requested.

Respectfully submitted,

Rebecca R. Barrett

Rebecca R. Barret
Reg. No. 35,152

Dated: February 16, 2001

Telephone: (610)-902-2646

02-20-01

GRP/1615

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PATENT

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FEB 16 2001
PATENT & TRADEMARK OFFICE

In re Patent Application of D.M.Sherman; J.C.Clark & J.U.Lamer

Serial No. 09/488,629 Examiner J. Spear

Filed January 20, 2000 Group 1615

For Extended Release Formulation CONFIRMATION NO. 4728

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

☐ No additional fee is required.

The fee has been calculated as shown below.

CLAIMS AS AMENDED							
		(2) CLAIMS REMAINING AFTER AMENDMENT		(4) HIGHEST NO. PREVIOUSLY PAID FOR	(5) PRESENT EXTRA	(6) RATE	(7) ADDITIONAL FEE
	TOTAL CLAIMS	* 25	MINUS	** 22	3	x $18.	54.00
	INDEP. CLAIMS	* 9	MINUS	*** 6	3	x $80.	240.00
	MULTIPLE DEPENDENT CLAIMS	0		0	0	$270.	0.00
				TOTAL ADDITIONAL FEE FOR THIS AMENDMENT →			294.00

* If the entry in Column 2 is less than the entry in Column 4, write "0" in Column 5.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
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☐ Fee for Terminal Disclaimer under 37CFR 1.20 (d) ($110.00) is also transmitted herewith.

☐ Fee of $_____ pursuant to 37 CFR 1.17(a) for extension of time under 37 CFR 1.136(a) is also transmitted herewith.

☒ Charge $ 294.00 to American Home Products Corporation Deposit Account No. 01-1425. Two additional copies of this sheet are enclosed.

☒ The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required by this paper to American Home Products Corporation Deposit Account No. 01-1425. Two additional copies of this sheet are enclosed.

Rebecca R. Barrett

Rebecca R. Barrett
Reg. No. 35,152
February 16, 2001

FORM PO-1033 (11-88)

USCOMM-DC 80425-P69

M2769-1N (12/00)

EXHIBIT W

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,** **Defendants.**	03-CV-1293 (WJM) **OPINION**

Kevin J. McKenna, Esq.
Gibbons, Del Deo, Dolan,
Griffinger & Vecchione
One Riverfront Plaza
Newark, New Jersey 07102-5497

Basil J. Lewris
Linda A. Wadler
Barbara R. Rudolph
Finnegan, Henderson, Farabow,
Garret & Dunner, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413

Attorneys for Plaintiff

Allyn Z. Lite, Esq.
Michael E. Patunas
Lite DePalma Greenberg & Rivas, LLC
Two Gateway Center
12th Floor
Newark, New Jersey 07102-5003

Henry C. Dinger
Daryl L. Wiesen
Lana A. Shvartsman
Melissa L. Paddock
Goodwin Procter LLP

Exchange Place
Boston, Massachusetts 02109

Attorneys for Defendants

MARTINI, U.S.D.J.:

Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. ("Teva") appeal from the May 13, 2005 Order of Magistrate Judge Patty Schwartz denying Teva leave to amend their answers to include an affirmative defense of unenforceability due to inequitable conduct.[1] Magistrate Judge Schwartz held that Teva had not shown good cause for amending the Pretrial Scheduling Order pursuant to Fed. R. Civ. P. 16(b) and, therefore, denied Teva's motion. Judge Schwartz also rendered "observations" that Teva's proposed amendment was unduly delayed, unduly prejudicial to Wyeth, and futile, and thus would likely be denied under Fed. R. Civ. P. 15(a) as well. But, Judge Schwartz did so without affirmatively denying Teva's motion to amend under Rule 15(a). Teva appeals the May 13, 2005 Order, arguing that it is clearly erroneous and contrary to law pursuant to Fed. R. Civ. P. 72(a) and L. Civ. R. 72.1(c)(1)(A).

Background

This is a patent infringement action. Wyeth charges Teva with infringing three of its patents: U.S. Patent Nos. 6,274,171 B1 (the "'171 patent"); 6,419,958 B2 (the "'958 patent"); and 6,403,120 B1 (the "'120 patent"). These patents have substantially identical specifications and are directed to an extended release formulation of venlafaxine hydrochloride. Wyeth listed

[1]Although Teva USA and Teva Ltd. each submitted their own proposed amended answer, the parties refer to them collectively as "Teva," in the singular, for purposes of this appeal because both companies seek to amend their answers to include the same inequitable conduct defense. For the sake of consistency, the Court shall do so as well.

these patents in its Effexor® XR[2] New Drug Application ("NDA") No. 20-699, which is directed to the use of venlafaxine hydrochloride extended release capsules "for the treatment of depression including depression with associated anxiety." (Steiner Decl. Ex. 3 at WYETH 004-000003).

Teva, seeking to market a generic version of Effexor® XR, filed an Abbreviated New Drug Application ("ANDA") for an extended release venlafaxine formulation. As part of the ANDA process, Teva provided Wyeth with notice that Teva's ANDA contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV).[3] Wyeth then brought this action against Teva charging patent infringement on March 27, 2003.

Seven of the independent claims asserted against Teva claim a "method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis . . . ." '171 patent, claims 20, 22, 23; '958 patent, claims 1, 3, 4; '120 patent, claim 1. Support for that claim language is found in the specifications of the patents-in-suit:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. *Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.*

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[2]"XR" is the abbreviation for extended release.

[3]A Paragraph IV certification must disclose an ANDA applicant's basis for asserting that its generic product will not infringe the patents listed in the NDA, and/or the basis for asserting that the patent claims are invalid.

'171 patent, col. 2, ll. 46-55 (emphasis added).[4] Teva asserts that Wyeth misrepresented its invention to the U.S. Patent and Trademark Office ("PTO") by making the italicized statement above (hereinafter "the statement") without any clinical studies in support thereof, and, as a result, committed inequitable conduct. On February 22, 2005, Teva requested leave to amend its answers to add that affirmative defense of inequitable conduct.

Before addressing the Magistrate Judge's resolution of that motion, it is necessary to go back in time so that Teva's request can be viewed in its proper context. On June 30, 2003, the Court entered a Pretrial Scheduling Order establishing December 31, 2003 as the deadline for amendment of pleadings. The parties engaged in fact discovery and on October 31, 2003, Wyeth produced its NDA. The NDA disclosed all clinical studies concerning Effexor® XR conducted by or for Wyeth. After reviewing the NDA, "it raised a red flag"[5] for Teva that it may have an inequitable conduct claim. However, Teva did not seek to amend its answers before the deadline, nor did it request that the deadline be extended. Teva professes that its inaction was due to its inability to determine whether the clinical studies supported the statement without the benefit of taking additional discovery. (*See* Teva Reply Br. at 7).

By October 4, 2004, Wyeth had substantially completed its document production. Teva then deposed each of the four inventors. Each inventor allegedly "confessed ignorance concerning support for the statement in the patent[s]." (Teva Reply Br. at 4). Teva then noticed a 30(b)(6) deposition. Wyeth produced two 30(b)(6) witnesses in February 2005, and it was at

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[4]Because the patents have substantially identical specifications, the Court cites only to the specification of the '171 patent.

[5](5/9/05 Tr. at 6).

those depositions where Teva allegedly confirmed for the first time which studies Wyeth contends support the statement: 600B-208-US ("the 208 study"), 600B-209-US ("the 209 study"), and 600B-367-EU ("the 367 study"). Further, according to Teva, it was only after taking those 30(b)(6) depositions that it was able to confirm its suspicions that Wyeth had no support for the statement. And thus, Teva filed its motion for leave to amend in February 2005.

On May 9, 2005, at the hearing on Teva's motion, Magistrate Judge Schwartz denied Teva's request, holding that Teva failed to demonstrate good cause to modify the scheduling order under Rule 16. Judge Schwartz reviewed Teva's request under Rule 16 because of the June 30, 2003 Pretrial Scheduling Order, which established the December 31, 2003 deadline for amendment of pleadings. The Magistrate Judge was not persuaded by Teva's protestations that it could not reasonably have sought to amend its answers before the deadline. Rather, Judge Schwartz found that Teva had sufficient information – the NDA and its disclosure of all clinical studies – in October 2003 to assert an inequitable conduct defense based on lack of clinical study support. Judge Schwartz further found Teva's argument that it needed additional discovery to "confirm" the factual underpinnings of its inequitable conduct allegations to be unpersuasive: "Given that the NDA reflected all the studies that related to the XR formulation, there was really no need to wait until the end of fact discovery to investigate the claims it now seeks to lodge." (5/9/05 Tr. at 90).

Teva then appealed that decision. That appeal is now before this Court.

Discussion

A district court may reverse a Magistrate Judge's order if it finds the ruling clearly erroneous or contrary to law. *See* 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A). The district court is bound by the clearly erroneous rule as to findings of fact, while the phrase "contrary to law" indicates plenary review as to matters of law. *Haines v. Liggett Group Inc.*, 975 F.2d 81, 91 (3d Cir. 1992). According to the Supreme Court, "a finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948).

Rule 16(b) of the Federal Rules of Civil Procedure governs amendment of pleadings once a scheduling order has been entered. *See Eastern Minerals & Chem. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000).[6] Rule 16 provides that a scheduling order "shall not be modified except upon a showing of good cause and by leave of the district judge or, when authorized by local rule, by a magistrate judge." Fed. R. Civ. P. 16(b). Good cause depends on the diligence of the moving party. *Globespanvirata, Inc. v. Texas Instruments Inc.*, 2005 WL 1638136, *3 (D.N.J. Jul. 12, 2005). The moving party must show that despite its diligence, it could not reasonably have met the scheduling order deadline. *S&W Enters., LLC v. Southtrust Bank of Ala., NA*, 315 F.3d 533, 535 (5th Cir. 2003). Further, the absence of prejudice to the nonmovant is not a consideration under the good cause standard. *Globespanvirata, Inc.*, 2005 WL 1638136 at *3.

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[6]Because a request to modify a pretrial order is considered to be a procedural issue unrelated to the patent laws, it is reviewed under the law of the regional circuit. *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1262 (Fed. Cir. 2002).

Here, it is uncontested that a Pretrial Scheduling Order was issued on June 30, 2003 and that the Order established December 31, 2003 as the deadline for amendment of the pleadings. Consequently, Teva's motion for leave to amend its answers was properly considered under the Rule 16(b) "good cause" standard.

Teva argues that Judge Schwartz's finding that it was not diligent is clearly erroneous. Teva asserts that it could not have reasonably amended its answers before the December 31, 2003 amendment cutoff. According to Teva, it could not determine from Wyeth's NDA which three studies supported the statement. Teva offers two reasons why the NDA by itself was insufficient. (*See* Teva Reply Br. at 7). First, the NDA is directed to only one indication for Effexor® XR, the treatment of depression. However, other clinical studies, concerning other indications, could have provided support for the statement. Second, the NDA identifies studies other than the 208, 209 and 367 studies which Wyeth may have relied upon when making that statement. Put differently, Teva essentially argues that because the NDA contained more than 3 studies, and Wyeth may have relied on any group of three to make the statement, Teva had insufficient information before the amendment deadline to properly plead an inequitable conduct defense. As a result, Teva asserts that it needed to take additional discovery to determine Wyeth's alleged bases for the statement.

Teva's arguments are factually incorrect and, ultimately, unconvincing. In her thorough analysis stated on the record on May 9, 2005, Judge Schwartz found Teva had not been diligent before the amendment deadline:

> The Court has not been presented with any information as to why there was any confusion about whether the three studies in the NDA were different than those in the patent application . . . . Thus,

> it appears to this Court that there was sufficient information long before February 2005 . . . upon which Teva could have sought leave or at least could have come before this Court and sought an extension at that time. In short, it appears that, at least from October 2003, Teva had possession of the information upon which it now relies for its proposed amendment.

(5/9/05 Tr. at 89, 91). Teva's arguments fail to demonstrate otherwise.

First, the three studies Wyeth relied on in making the statement are easily recognizable. The patent refers to two eight-week and one-twelve week studies. The NDA discloses three completed studies: the 208, 209 and 367 studies. The 208 and 209 studies were eight weeks in length, while the 367 study was twelve weeks in length. Teva argues that it could not have known that these were the three relevant studies because there are two other eight-week and one other twelve-week studies. (Teva Reply Br. at 2 (citing Steiner Decl. Ex. 3 at WYETH 004-000079-81)). However, and Teva should have known this, at the time those studies were reported in the NDA, "[n]o interim data [were] available." (Steiner Decl. Ex. A at WYETH 004-017122, 19080, 17206). Thus, Teva has presented no reasonable explanation why those three studies caused it any confusion when trying to ascertain which studies support the statement.

Teva also argues that it could not have known which studies were relied upon because the NDA includes "[o]ther studies of unidentified length" which were ongoing. (Teva Reply Br. at 3 (citing Steiner Decl. Ex. 3 at WYETH 004-000077-78)). Those other studies, Teva posits, could have been eight or twelve weeks in duration and, therefore, they potentially could have been support for the statement. However, an examination of the pages cited by Teva reveals that the duration of those studies was "6-12 mos". (*Id.*). Not surprisingly, Teva fails to explain why it confused those two studies with the 208, 209 and 367 studies.

In short, none of the five additional studies that allegedly caused Teva confusion could have been relied upon by Wyeth to show a statistically significant improvement. Further, Teva does not identify any other study that could have been confused with the 208, 209 and 367 studies. Therefore, Teva's assertion that it could not reasonably determine which three studies supported the statement is belied by the NDA.

Second, and more importantly, Teva's inequitable conduct theory by itself eliminated any potential confusion Teva may have had regarding Wyeth's support for the statement. Teva's inequitable conduct theory is predicated on the assertion that the statement – "[v]enlafaxine ER showed a statistically significant improvement . . . in [three] studies" – required "that three studies *each* showed a statistically significant improvement." (Teva's Reply Br. at 7, emphasis added). According to Teva, in order to show a statistically significant improvement, a clinical study would need to compare the extended release product with the immediate release product. (*See Id.* at 8). But only one study disclosed in the NDA – the 208 study – made such a comparison. And Teva claims that that study did not show a significant improvement; rather, it "showed the *same* incidence of nausea for both formulations (45%)." (Teva Reply Br. at 8, emphasis in original). Further, Teva acknowledges that "[n]othing on the face of the [studies] themselves indicate that they provide support for any conclusion about 'statistical significance.'" (*Id.*). Consequently, because under Teva's theory of inequitable conduct none of the clinical studies disclosed in the NDA support the statement, and that should have been evident after Teva

reviewed the NDA, Teva provides no reason why it could not have asserted its inequitable conduct defense before the amendment deadline.[7]

Teva responds that because allegations of inequitable conduct are serious, and because inequitable conduct must be plead with particularity under Fed. R. Civ. P. 9, Teva acted appropriately by conducting additional discovery to confirm the factual underpinnings of its defense.[8] Although the Court agrees with Teva that no party should blithely assert a charge of inequitable conduct, nor should a party attempt to plead inequitable conduct if it is unable to do so with particularity,[9] the Court is not convinced that the Magistrate Judge erred when determining that Teva did not act diligently under the circumstances in this case. Certainly, in some cases it may be appropriate to conduct additional discovery to ascertain or develop an

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[7]Teva's argument that Wyeth did not disclose that the statement was based on a "pooled" analysis of the three studies until February 2005 is irrelevant. Regardless of what Wyeth's justification was for that statement, Teva knew before the deadline that Wyeth could not be relying on three studies that each performed a comparative analysis because the NDA, which was required to contain all relevant clinical studies, did not include three such studies. Thus, Teva did not need to know that Wyeth relied on a "pooled" analysis before raising its inequitable conduct defense.

[8]In support of this argument, Teva cites three district court cases: *Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484 (D. Del. 2003); *Douglas Press, Inc. v. Int'l Gamco, Inc.*, 2004 U.S. Dist. LEXIS 7606 (N.D. Ill. May 3, 2004); *Go Med. Indus. Pty Ltd. v. C.R. Bard, Inc.*, 1995 U.S. Dist. LEXIS 22248 (N.D. Ga. July 5, 1995). Those cases, however, are inapt. First, all of the cases decided a motion for leave to amend to add an inequitable conduct defense in the first instance. None reviewed the decision of a Magistrate Judge under the deferential standard elucidated by Rule 72. Second, the last two cases, *Douglas Press* and *Go Medical*, were decided under the more permissive Rule 15(a), not under Rule 16(b). And third, although *Enzo Life Sciences* was decided in part under Rule 16, the Court expressly found that the inequitable conduct theory was based on a new set of facts discovered after the amendment cutoff date. 270 F. Supp. 2d at 489.

[9]*See Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (stating that "inequitable conduct, while a broader concept than fraud, must be pled with particularity").

inequitable conduct defense before requesting leave to amend. However, this was not such a case. In short, Teva has failed to demonstrate that Judge Schwartz's decision was clearly erroneous or contrary to law.[10]

Conclusion

For the reasons stated above, Magistrate Judge Schwartz's Order dated May 13, 2005 is affirmed.

Dated: August 3, 2005

s/ William J. Martini
William J. Martini, U.S.D.J.

[10]Having affirmed the holding that Teva did not show good cause to modify the Pretrial Scheduling Order under Rule 16(b), the Court need not address Judge Schwartz's "observations" of undue delay, prejudice and futility under Rule 15(a).

EXHIBIT X

ENTIRE EXHIBIT REDACTED

EXHIBIT Y

ENTIRE EXHIBIT REDACTED